AVANCEN

IMPROVING PATIENT CARE AT THE BEDSIDE®

# MOD® INSTRUCTIONS FOR USE



**Avancen MOD Corporation**
**Medication on Demand (MOD®)**
**Oral Drug Delivery System**

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Document Reorder Number: Instructions for Use V1

# Classification and Approvals

This medical device is classified with respect to electric shock, fire and mechanical hazards only in accordance with:



WITH RESPECT TO ELECTRIC SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1

MET Laboratories Inc. has evaluated Medication on Demand (**MOD**® ) with respect to UL 60601-1 for General Standards of Safety for Medical Equipment and found the **MOD**® **to be compliant.**

| | |
|---|---|
|  | Alternating current electricity only (utility-supplied electricity). |

| | |
|---|---|
|  | This manual contains important instructions you should read prior to use. |

| | |
|---|---|
|  | Dangerous voltage. Follow all instructions. |

| | |
|---|---|
|  | Direct current. |

| | |
|---|---|
|  | Class II equipment. |

This device is an approved FDA Class I medical device, 510(k) exempt, manufactured in accordance with applicable CFR FDA requirements.

**Disclaimer**
**The information in this document is subject to change without notice. While the information contained is accurate to the best of our ability, Avancen MOD Corporation assumes no liability or responsibility for omissions or errors.**

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# Warnings and Cautions

These Instructions for Use contain important product information, instructions for use and operation. PLEASE SAVE THESE INSTRUCTIONS. The IFU is also available in electronic form through the Avancen website, www.avancen.com.

**IMPORTANT**

Health care professionals should read this entire Instructions for Use before operating or putting into use the Avancen MOD® medication delivery system. Before using the MOD® device you must read and thoroughly understand the warnings, cautions, and operating instructions contained herein.

**FOR HELP**

If you have questions about the information in these Instructions for Use or about operation of the MOD® system, review the "Help" information at www.avancen.com or call Customer Service at 1-800-607-1230. The Model and Serial Number for your MOD® device are located on the back of the unit and the serial number is easily visible in the center of the clear medical grade plastic cover.

## Indications for Use

The MOD® device is a patient-controlled drug delivery system designed to provide safe, secure, and accurate delivery of oral tablet or capsule medications in supervised hospital, clinical, or institutional settings as prescribed by a physician or other licensed prescriber. MOD® is designed to provide qualified patients access to their own prescribed oral pain medications "as needed" (PRN) at the bedside while under the supervision of professional healthcare staff. MOD® supports regulatory compliance by keeping a detailed record of oral PRN medication accessed and electronically records patient pain levels on a numeric pain scale. The MOD® device is not a substitute for monitoring of patient compliance or establishing the efficacy of the patient's pain orders within the clinical setting by licensed professionals. The purpose of MOD® is to support the delivery of PRN medications in a healthcare setting. Do not use the MOD® device for any purpose that does not comply with its stated indications for use.

## Warnings

1. **ROUTINELY INSPECT EACH MOD® DEVICE PRIOR TO USE. DO NOT USE A MOD® DEVICE, MOD® MEDICATION TRAY, SECURITY HOLDER, OR ANY MOD® ACCESSORY THAT SHOWS ANY SIGN OF DAMAGE, TAMPERING, OR IMPROPER FUNCTION. IF THE MOD® HAS BEEN DROPPED AND HAS SUSTAINED PHYSICAL DAMAGE, DO NOT PUT THE DEVICE INTO USE AND RETURN IT TO THE APPROPRIATE SOURCE (EITHER BIOMEDICAL ENGINEERING OR AVANCEN MOD CORPORATION) TO INSPECT OR SERVICE THE DEVICE.**

2. **USE OF THE MOD® DEVICE IS NOT INDICATED FOR THE ADMINISTRATION OF ANY EMERGENCY OR LIFE-SUSTAINING MEDICATIONS.**

3. **USE THE MOD® DEVICE TO DELIVER ORAL TABLET OR CAPSULE MEDICATION FORMULAS ONLY. THE MOD® IS NOT INDICATED FOR THE DELIVERY OF ANY LIQUID, INJECTABLE, PATCH, OR POWDER DOSAGE FORMS OF MEDICATION. ATTEMPTING TO LOAD AND DELIVER THESE SUBSTANCES WILL DAMAGE EITHER THE MOD® DEVICE AND/OR THE MEDICATION AND WILL VOID ALL WARRANTY CLAIMS OF THE DEVICE.**

4. **THE MOD® DEVICE USE IS BY <u>PHYSICIAN ORDER ONLY</u>.**

5. **A HEALTHCARE PROFESSIONAL MUST VERIFY THAT THE USER IS CAPABLE OF UNDERSTANDING HOW TO OPERATE THE MOD® DEVICE ACCORDING TO THE INSTRUCTIONS CONTAINED WITHIN THIS USER MANUAL AND BE ABLE TO DEMONSTRATE HOW TO ACCESS MEDICATIONS FOR SELF-ADMINISTRATION FROM THE DEVICE.**

6. **USE OF MOD® DEVICE IS NOT INTENDED AS A REPLACEMENT OR SUBSTITUTE FOR A HEALTHCARE PROFESSIONAL'S RESPONSIBILITY TO MONITOR, EVALUATE, AND ASSESS A PATIENT'S ONGOING CARE AND TO DETERMINE THE EFFICACY OF THE PATIENT'S PAIN THERAPY.**

7. **WHEN PROGRAMMING THE MOD® DEVICE, ENSURE THAT THE CORRECT PATIENT/USER PROFILE, MEDICATION, AND MEDICATION DISPENSE ORDER ARE BEING USED PRIOR TO INITIATING THERAPY WITH THE MOD® DEVICE. FAILURE TO USE THE APPROPRIATE PATIENT USER PROFILE AND MEDICATION DISPENSE ORDER COULD RESULT IN SERIOUS HARM. DO NOT USE THE MOD® DEVICE IN ANY WAY THAT IS NOT CONTAINED WITHIN THESE INDICATIONS FOR USE AND IN COMPLIANCE WITH THE PRESCRIPTION OR DIRECTIONS OF YOUR PRESCRIBING MEDICAL PRACTITIONER, PHARMACY, OR DRUG MANUFACTURER.**

8. **USE ONLY APPROVED DISPOSABLE EIGHT-DOSE SINGLE USE MOD® MEDICATION TRAY AND SEALS. THESE ARE THE ONLY DISPOSABLE TRAYS/SEALS APPROVED FOR USE.**

9. **DO NOT REUSE PREVIOUSLY USED MOD® MEDICATION TRAYS. MOD® MEDICATION TRAYS ARE DESIGNED FOR SINGLE USE ONLY. DISPOSE OF TRAYS AND ANY REMAINING MEDICATION AFTER EACH USE IN ACCORDANCE WITH INSTITUTIONAL POLICIES AND PROCEDURES AND REGULATIONS APPLICABLE TO THE STORAGE, DELIVERY, AND RECONCILIATION OF THE USE OF CONTROLLED SUBSTANCES AND OTHER MEDICATIONS.**

10. **ALWAYS LOCK AND SECURE THE MOD® DEVICE AFTER LOADING MEDICATION ACCORDING TO THE USER GUIDE AND INSTRUCTIONS.**

11. **BIOMEDICAL PERSONNEL SHOULD INSPECT THE MOD® DEVICE. IF IT HAS BEEN DROPPED, SEVERELY JARRED, OR HAS EVIDENCE OF PHYSICAL DAMAGE, IMMEDIATELY REMOVE THE DEVICE FROM PHYSICAL USE AND REPORT THE PROBLEM TO AVANCEN SERVICE PERSONNEL AND DISCONTINUE USE OF THE DEVICE UNTIL THE PROBLEM HAS BE IDENTIFIED AND CORRECTED.**

12. **TO PREVENT ELECTRICAL HAZARDS, UNPLUG THE MOD® DEVICE BEFORE CLEANING. USE ONLY APPROVED CLEANING AND DISINFECTION METHODS DESCRIBED IN THIS USER MANUAL. DO NOT SPRAY CLEANSERS INTO THE ADAPTER POWER CORD RECEPTACLES. DO NOT EMMERSE THE MOD® DEVICE IN ANY LIQUID. CLEAN AND DISINFECT ONLY USING A "WIPE DOWN" METHOD AND ALLOW THE DEVICE TO DRY COMPLETELY PRIOR TO USE.**

13. **WHEN USING THE A/C ADAPTER, CONNECT THE PLUG ONLY INTO A GROUNDED A/C OUTLET.**

14. **SHOULD THE MOD® DEVICE MALFUNCTION OR NOT PROPERLY OPERATE AS DESCRIBED IN THIS USER MANUL, IMMEDIATELY REPORT THE PROBLEM TO**

**BIOMEDICAL ENGINEERING OR AVANCEN SERVICE PERSONNEL AND DISCONTINUE MOD® DEVICE USE UNTIL THE PROBLEM CAN BE IDENTIFIED AND CORRECTED.**

15. **DO NOT USE ANY MOD® DEVICE OR MOD® ACCESSORY IF ITS PACKAGING APPEARS TO BE DAMAGED OR OPENED. INSPECTION AND REPAIR OF ANY DAMAGED DEVICE MUST BE DONE ONLY BY AVANCEN MOD CORPORATION OR ITS CERTIFIED AGENTS. ANY UNAUTHORIZED ACCESS TO OR ATTEMPT TO SERVICE THE MOD® DEVICE BY UNAUTHORIZED PERSONS SHALL VOID THE WARRANTY. AVANCEN MOD CORPORATION ASSUMES NO RESPONSIBILITY OR LIABILITY FOR SERVICE BY UNAUTHORIZED PERSONS.**

16. **DO NOT USE THE MOD® DEVICE OR ANY OF ITS COMPONENTS UNTIL YOU HAVE READ AND COMPLETELY UNDERSTAND THE INSTRUCTIONS AND INDICATIONS FOR USE IN THIS USER MANUAL.**

17. **REFERENCES IN THIS MANUAL TO SPECIFIC DRUGS AND DRUG DOSES ARE FOR ILLUSTRATION PURPOSES ONLY AND ARE NOT MEANT TO PROVIDE GUIDANCE ON THE PRESCRIBING, USE, OR DELIVERY OF CONTROLLED SUBSTANCES.**

## Cautions

**CAUTION!**
**THE MOD® DEVICE IS NOT INTENDED TO REPLACE TRAINED PERSONNEL IN THE SUPERVISION OF, USE OF, AND DELIVERY OF MEDICATIONS.**

1. **CAREFULLY READ AND FOLLOW MOD® SYSTEM AND PROGRAMMING INSTRUCTIONS IN THIS MANUAL. USE ONLY SPECIFICALLY APPROVED ACCESSORIES WITH THE MOD® DEVICE. USE OF UNAPPROVED ACCESSORIES COULD AFFECT ACCURACY OF DRUG DELIVERY OR MAY RESULT IN INJURY TO PATIENT.**

2. **TO PREVENT DAMAGE TO MOD® EQUIPMENT, USE ONLY THE SUPPLIED A/C ADAPTER WHEN POWERING THE MOD® DEVICE.**

3. **DO NOT ATTEMPT TO OPEN THE MOD® DEVICE HOUSING OR CASE. THE MOD® DEVICE IS CONSIDERED AN LRU (LOWEST REPLACEABLE UNIT); THEREFORE, THERE ARE NO REPAIRABLE COMPONENTS IN THE SYSTEM. WHEN THE UNIT IS NOT WORKING PROPERLY, RETURN THE UNIT TO AVANCEN MOD CORPORATION FOR INSPECTION AND REPAIR IF NEEDED. ONLY AVANCEN AUTHORIZED SERVICE PERSONNEL SHOULD REPAIR THE MOD® DEVICE OR ITS ACCESSORIES. AVANCEN AND/OR ITS CERTIFIED AGENTS ASSUME NO RESPONSIBILITY FOR ANY DAMAGES OR LIABILITIES THAT MAY OCCUR IF THE MOD® DEVICE IS SERVICED BY NON-AUTHORIZED PERSONNEL.**

4. **KEEP MOD® DEVICE SURFACE CLEAN, DRY, AND FREE OF FLUID SPILLAGE AT ALL TIMES. INSURE THAT THE MOD® DEVICE IS CLEANED AND DISINFECTED BETWEEN PATIENTS PER INSTITUTIONAL PROCEDURES AND GUIDELINES.**

5. **THE MOD® DEVICE IS FLUID RESISTANT AND CAN WITHSTAND MINOR FLUID SPILLAGE. HOWEVER, IT IS NOT DESIGNED FOR TOTAL IMMERSIONS SINCE MOISTURE INTRUSION TO THE DEVICE WITHIN THE CASE COULD CAUSE DAMAGE TO THE OPERATING COMPONENTS. DO NOT PLACE THE MOD® DEVICE IN THE SHOWER, BATH, OR SAUNA/STEAM BATH. DO NOT SUBMERGE THE MOD® DEVICE IN WATER OR OTHER LIQUID. DO NOT POSITION THE MOD® DEVICE WHERE IT COULD ACCIDENTALLY BE DROPPED INTO A CONTAINER OF FLUID (E.G., BASIN, TUB, OR TOILET). AVOID FLUID CONTACT WITH POWER PORT AND DATA PORT OF THE MOD® DEVICE.**

6. **THOROUGHLY CLEAN AND DISINFECT THE MOD® DEVICE AFTER AND BETWEEN EACH PATIENT USE.**

7. **DO NOT CLEAN, DISINFECT, OR STERILIZE ANY PART OF THE MOD® DEVICE BY AUTOCLAVING. THIS MAY DAMAGE THE MOD® DEVICE AND WILL VOID THE WARRANTY.**

8. **DO NOT GAS STERILIZE THE MOD® DEVICE. THIS MAY DAMAGE THE MOD® DEVICE AND WILL VOID THE WARRANTY.**

9. **DISINFECT THE MOD® DEVICE'S EXTERNAL PARTS ONLY, USING APPROVED CLEANSERS OR DISINFECTANTS ACCORDING TO THE INSTRUCTIONS PROVIDED IN THIS MANUAL.**

## Introduction - MOD® Device Components



Medication carousel

Medical grade plastic cover and housing

Lighted backlit faceplate; RFID reader behind center "Dancing Man" logo; Ready indicator and wireless indicator.

This picture identifies MOD® components as they are referred to throughout this User Guide.

## About the System – Work Flow Summary

The MOD® medication delivery process is by a licensed prescriber clinician order only. A clinician will prescribe a specific oral pain medication to be given PRN, using MOD®, indicating the required lockout time interval between doses and an immediate dose time ("now" or clinician dose) interval if desired.

The pharmacy will manually fill, cover, and label a disposable medication tray for the device with eight identical doses of the prescribed medication. A barcode label may be attached to the center portion of the tray by pharmacy. The sealed labeled medication tray is delivered to the appropriate medical unit for loading into the MOD® device.

The nurse or pharmacy personnel program the MOD® device wirelessly through a software interface that utilizes the institution's network to access the MOD® device. As part of initiating new therapy with a new patient, the nurse or pharmacy personnel programs a patient RFID (Radio Frequency Identification) tagged wristband or wristwrap that is proprietary to the MOD® device. The RFID wristband is the only item that provides access to the external device and medications and serves to associate only one device with one particular patient to provide security of access by only that patient. Next, the nurse/pharmacy programmer enters the patient's medical identification number or code (up to 16 alpha/numeric characters are possible), the medication or prescription order number (if available), chooses the prescribed medication and the dose and lockout time interval in hours (the time between subsequent doses), and *now* dose interval if ordered for the patient.

Figure 1: Nurses or pharmacy personnel program the MOD® device using the easy-to-follow software wizard

As part of and within the new patient programming step, the top medical grade plastic cover is automatically opened, and the programmer loads the filled tray into the device, pulls off the tray cover that protects and secures the medications, and closes the MOD® medical grade plastic cover securely. Once the MOD® device is programmed and loaded, it is attached using a secure, unique and proprietary pole clamp to an IV pole (Figure 2). Please note: MOD® may also be programmed while attached to the IV Pole. Programming/loading area is best determined by the individual location based on optimal work flow per each care area. Once programmed and loaded, MOD® is delivered to the patient bedside where it remains next to the patient for easy access and delivery of the patient's pain medications.



Figure 2: MOD® device IV pole security holder

When the patient experiences pain, he/she looks for the green READY light on the front panel of the MOD® device. If the prescribed and programmed time interval has elapsed, the green READY light will illuminate, indicating that the patient can access a single dose of the medication.
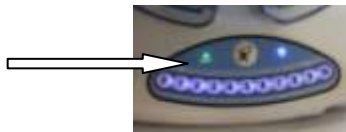


Figure 3: Green READY light signals patient when the prescribed time interval has finished and the patient can remove the prescribed medication.

To access the as-needed medication, the patient touches a number on the illuminated pain scale panel ranging from a value of 0 to 10 on the MOD® device Pain Scale to document his/her current level of pain (Figure 4). Touching the Pain Scale panel activates the device's internal RFID reader, and the green READY light will blink with an accompanying audible continuous "tone".

Figure 4: Patient touching Pain Scale to record the level of pain on a 0-10 scale (zero being the least amount of pain; 10 being the greatest amount of pain)

Next, the patient places his/her assigned RFID wristband within an inch of the MOD® device's front panel where the internal RFID reader is located (Figure 5). The patient should not wave or sweep the wristband/wristwrap over the device, but hold the RFID portion of the

wristband/wristwrap over the "Dancing Man" (  )  logo area on the lighted faceplate.



Figure 5: Patient holds the RFID wristband over the front panel

Once the MOD® device identifies the RFID wristband and verifies the patient's identity, the device will move the medication carousel forward, exposing a single dose of medication to the patient. The patient can easily remove the medication with his/her fingertip (Figure 6).



Figure 6: Patient removing prescribed medication dose from the MOD® device.

After a brief period (sufficient for the patient to remove the tablet or capsule - the slot remains open for 45 seconds), the medication tray rotates to a closed position and relocks. The MOD® device remains closed and inactive until the next prescribed dosing interval arrives. If the patient does not yet need the medication after the lockout time interval, the device remains locked with the green READY light on, indicating that it is ready to respond when the patient desires another dose of the medication.

Additional software programs are available for the nurse or programmer to interact with the device to obtain information or revise the program within the device. These include the Modify/Reload program, the Dispense Now program, and the Discharge program to remove the patient data from the device to prepare the device for another patient's use. See detailed procedures under Operating the MOD® for the use of these programs.

**CAUTION!**
**DO NOT USE THE MOD® DEVICE TO DELIVER LIQUID OR POWDER MEDICATIONS. THE MOD® DEVICE ONLY DELIVERS ONLY ORAL TABLET OR CAPSULE MEDICATIONS.**

## Special Features

The Medication on Demand (MOD®) system contains the following special features:

### Integrated Non-Rechargeable Battery

**The MOD® device is a mains operated equipment with an additional power source of a non-rechargeable battery, but should not be used when disconnected from power.** The device should remain plugged in to a three-pronged grounded outlet allowing the device and the patient maximum mobility while using the device for pain management. The MOD® supplied A/C adapter has a knurled thread to secure the connection. When the MOD® is disconnected from the supplied A/C adapter, an audible ping will occur every three seconds. **Use only the medical rated power supply A/C adapter that is shipped with the MOD® device. Use of any other A/C power supply units may damage the device and will void the warranty. If the MOD is not likely to be used for some time, the primary battery should be removed. The primary battery is 9 V LA522. The coin cell battery is 3 V FDK CR2032v.**

### On/Off Switch

The MOD® device is designed with an on/off switch, located on the back side of the device. The button is pushed in to turn "on" and pushed a second time to turn "off" the device. The button is "off" in the extended position and "on" when the button is in the depressed position. It is recommended that the device should be turned "off" when not in use by a patient. Devices in use (with a patient) that are turned "off" for any reason (should a patient leave the room, for example) will restore all functions and operate normally when returned to operating state as they are equipped with internal battery backup and memory to retain the programming.

### Signals and Alerts

There are two LED light areas on MOD® device's front panel. On the left side of the MOD® device is a READY light which glows green when the device is ready for patient use. The green READY light notifies the patient that the appropriate time interval has passed and that she/he can access the prescribed medication. When the READY light is off, the required lockout interval has not yet passed, and consequently, the patient cannot access the medication. The green READY light also blinks following specific tasks, as described in the detailed operating procedures, to notify the user that an operation sequence is in progress. The second light on the MOD® device is the WIRELESS connection light. When the device is turned on, this light turns from red to blue to indicate that the device has established a connection to the institution's wireless network. The wireless connection light will turn from blue to green when connected to the programming software and during the programming sequence.

### Integrated Pain Scale and RFID Activation



Figure 7: MOD® device Backlit Pain Scale 0 to 10

The MOD® device incorporates an integral backlit illuminated numeric Pain Scale for the patient to record his/her pain level during established periods. (Figure 7). Pressing any of the lighted numeric buttons on the Pain Scale activates the RFID reader located under the Avancen logo button in the center of the MOD® device blue faceplate area. Once the RFID reader is activated, the patient holds his/her RFID programmed wristband or wristwrap in front of the MOD® device's reader until recognized by the device. Once the reader recognizes the wristband or wristwrap, it activates the dispenser wheel to turn and exposes one dose of medication. The numeric Pain Scale is for documentation only as part of the medication request process. The MOD® device records the patient's pain level input, the date, and the time of the medication dose delivery and self administration. All medication delivery data is recorded and stored in the MOD® device's proprietary database which resides on an appropriate institution server and any data can be retrieved for permanent entry into the patient's medical record by an authorized user on the network with the appropriate authority/access level. NOTE: For evaluations, the system will be housed independently on the institution's server. Nursing will print patient information (as needed/requested) and manually enter the information into the patient's electronic medical record as currently required by institution practices. It is planned to offer full integration with the patient's electronic medical record at some time in the future.

## Easy Dispense Order Programming

The MOD® user-friendly programming wizards provide icons, screens, and guides that allow the healthcare professional to program and operate the device easily.

## Tamper Resistant Features

The MOD® device has a high-density, clear medical grade plastic cover that closes and securely locks over the medication tray insert. To physically lock the MOD® device cover, the nurse presses down firmly on the cover until the sturdy spring-loaded lock engages and locks the cover. To unlock the MOD® cover (devices that are in use for patients), the nurse must use the MOD® programming software. To open the cover on non-programmed devices (i.e., a device that has not been assigned to a patient), the nurse presses and holds the zero button on the faceplate until the tone is heard and then the zero is released and the tray will turn and the cover will open. These multiple security features are designed to control access to the medication tray and make it tamper resistant from unauthorized personnel and patients.

## Anti-Theft Feature and Device Securement

Each MOD® device comes attached to a security bracket/clamp mechanism that in turn is locked onto an institution's intravenous (IV) pole. This locked security bracket stabilizes the MOD® device, prevents breakage, and deters theft of the device and its contents. Access to the locking system is by a unique proprietary key provided with the MOD® device. The key should be placed in a secure location that is only allowed access by authorized personnel.

## Radio Frequency Identification (RFID) Technology for Added Security

The patient wristband (wristband in this instance refers to both the Avancen-supplied proprietary RFID wristband or wristwrap) and employs radio frequency identification (RFID) technology to ensure that only the patient who is wearing a wristband previously associated with the device can access the MOD® device at the bedside. The wristband is registered to a MOD® device and is associated only with that device as part of a new patient programming sequence. It remains as the only entry to the associated device until the patient is discharged from the device. Once discharged, the RFID wristband no longer operates the device and cannot be used to access the device and should not be reused for patient use.

The MOD® device contains an RFID reader platform. The RFID reader is activated when the patient presses the number on the Pain Scale that corresponds to their pain level, and when the

nurse assigns a new patient to the device. The reader is a **low-power 13.56 MHz module with an on-board antenna**.

Passive RFID tags are incorporated into the patient wristbands. These RFID tags have no internal power source. The range for reading the RFID tag is within 1 inch of the reader, which precludes any significant electromagnetic interference (EMI) from other systems or interference with other systems.

## Auditory and Visual Alert Features

The MOD® device provides auditory and visual cues and alerts for both the clinicians and patients. For instance, during a programming sequence, if a command has been completed successfully, the device emits an auditory chime to confirm that the step has been completed ("a bing"). If the step has not been completed successfully (for example, when programming a particular wristband to a particular device), the device emits a distinctly different tone ("a bong") indicating that the step has not been completed correctly and the programming step will not advance. Another example is the use of the ready light on the front panel of the device. When the next dose of medication is available, the ready light will illuminate green to indicate that the next scheduled dose of medication is available to the patient. If the ready light is dark (not illuminated), this indicates that the patient is within the lockout period BETWEEN doses and cannot access the medication.

## Fluid Resistant

The MOD® device medical-grade plastic body, cover, and enclosure are fluid resistant and designed to prevent fluid intrusion.

## Ease of Tablet Delivery

The MOD® device's ergonomic medication tray design allows the patient to easily remove the medication dose with a finger. There is no need to pick up or move the device. It should be noted that manual dexterity is a requirement to qualify a patient for placement on a MOD® device. Should a patient have constraints or impairments in moving his or her arm, extending a finger to grasp, hold, and deliver a pill, they would not be appropriate patients to utilize a MOD® device for self-administration of PRN pain medications.

## Detailed Recording of Medication Use

While the MOD® device is operating and is in use by a patient, it periodically uploads the patient's information into the MOD® database which is resident on an appropriate institution or institutional network server. NOTE: during product evaluations, the information will be uploaded and stored on the institution server. Manual individual patient data entry into the electronic medical record (EMR) is required at the current time; it is planned in the future to provide for direct integration from the MOD® data base into each patient's EMR. The following data is provided:

- The patient identification number and initial Medication Dispense Order (also known as a Prescription Order).

- The date and time of each patient medication removal event.

- The patient's numeric Pain Scale level at each medication request removal event.

- The patient's self-reassessment of his/her pain level. The MOD® device has a built-in customizable reassessment feature which, via an auditory voice command and visual alert (gentle pulsing light) notifies the patient to input a reassessment of his/her pain level between dosing intervals, normally recommended at a one-hour interval. After prompting, the patient presses the appropriate numeric back-lit button, indicating his/her current level of pain and the device automatically records and transmits the data to the MOD® database.

- The date and time of each nurse override event to dispense unscheduled doses or clinician doses, frequently called "now" doses.

- The date and time for each instance that the cover of the device is unlocked by the nursing staff.

- **SPECIAL NOTE:** The computer used to program the device must have the correct time zone to accurately transfer time/date information to the MOD® device's memory.

## Patient Responsibility and Patient Selection

The MOD® Oral Drug Delivery System should be made available only to patients who are proper candidates for the use of the device. Recommended guidelines subject to each institutional policy are that patients should be:

- Awake

- Alert

- Able to accept device responsibilities and retain basic instruction on device use

- Without a diagnosis of dementia or any other condition affecting cognitive ability

- Without swallowing difficulties

- Without a history of drug abuse or drug seeking behavior

- Without a physical disability to prevent use

- Able to comfortably reach the device, take a pill out of the device, and bring it to the mouth.

This patient commitment includes the requirement to report any device malfunction to the nursing or facility staff, and to not allow any of their prescribed medication to be tampered with or diverted to anyone other than themselves. The nursing staff should remove the MOD® device from any patient who appears to be incapable or irresponsible in handling the device or its contents. The nursing staff is cautioned to review a brief patient education module with the patient prior to the initiation of the device use. See a sample Patient MOD® Use Checklist in the Appendix.

## Initial Setup

Each MOD® is manufactured to precise quality standards. However, improper handling in transit could result in damage to the device. Always fully inspect the MOD® device and its accessories for any sign of damage before using. Promptly notify Avancen MOD Corporation of any observable damage upon incoming inspection and do not utilize any device with obvious packaging damage.

### Unpacking the MOD®

Prior to initial use, unpack MOD® and its accessories as described below:

- Remove the MOD® device from its carton.

- Verify that the MOD® housing, cover, sensors, and touchpads are intact and not damaged.

- Verify that the MOD® Security Bracket attached to MOD® is intact and not damaged.

- Verify that the MOD® adapter unit and cord are not damaged, cut, or deformed.

- Verify that the IV pole clamp is intact with the appropriate number of screws for attachment to the security bracket.

- Locate the security key lock wrench.

- Check all components for loose or damaged parts.

- Perform periodic inspections of the MOD® unit and its accessories (see Maintenance & Cleaning section).

If the MOD® device or any of its accessories appear damaged, notify the shipping carrier immediately. In addition, contact Avancen to obtain return authorization for repair or replacement.

## Storing the MOD®

After unpacking the MOD® device, store it in a clean, dry environment with the following conditions, which are also the recommended operating environment for the MOD®:

- 10º C to +40º C (50º F to +104º F) temperature

- 20% to 75% relative humidity (non-condensing)

- 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure

## Cleaning the MOD® Prior to First Use and Check-in Procedures

The MOD® device should be thoroughly wiped down prior to its first use. See the section on Maintenance and Cleaning in the User Manual for complete instructions on cleaning the MOD® device.

Clean the MOD® device security bracket holder, and the clamp with a soft, slightly damp cloth, using one of these low-level institution disinfectants. Follow the commercial product directions for dilution and proper usage. Dry the device with a clean cloth or paper towel.

Per your institutional guidelines, perform required check-in and labeling by Biomedical Engineering prior to putting device into use.

| Approved Cleansers |
| --- |
| Ethyl or Isopropyl Alcohol (70-90% V/V concentration) wipes |
| A solution of 10% (V/V) sodium hypochlorite in water |
| Chloride-based cleaners |
| Soap solution (to remove visible or known organic matter) |
| Hydrogen peroxide 3% |

Clean any electrical connection areas, if soiled, with ethyl or isopropyl alcohol swabs. NOTE: Before cleaning any electrical connection area, unplug the unit from the power source. Never clean a power supply area that is active (plugged into an electrical outlet).


Use the following steps to clean the device:
- Using any of the above appropriate cleaners, wipe down all surfaces of the device including the top cover, keypad and panel and all external surfaces, as well as the clamp mount to IV pole.
- Use caution to avoid any contact with electrical connections and contacts on the rear of the device.
- Wipe clean only; do not immerse the device in liquid of any kind as immersion can cause severe damage to the device and will void its warranty.
- Clean any electrical connection areas, if soiled, with ethyl or isopropyl alcohol swabs. Make sure electrical connections are no longer active (unplugged) before cleaning.

- Disposable trays and seals are not designed for re-use and should NOT be cleaned. They are single patient use only!
- Allow wiped surfaces to dry completely prior to use.

## MOD® Starter Kit

The MOD® device is delivered with key components essential to optimize its use. Every MOD® device starter kit is shipped with:

- One (1) A/C adapter (power supply/power cord)

- Mounting security bracket which comes already attached to the device

- IV pole clamp, mounting screws and security key. Device is shipped with IV pole clamp attached to the device

- MOD® device User Manual (CD format)

A customized order can be made to provide a sufficient number of MOD® device security locking tools, and RFID wristbands or wristwraps to your healthcare facility to begin operation of all MOD® devices procured. Additional RFID wristbands/wristwraps, and security locking tools are available at an additional cost from Avancen (1-800-607-1230), or from your facility's procurement organization or group purchasing organization (GPO).

## Assembly of the IV Pole Clamp onto the Security Bracket

The MOD® device is packaged at the factory attached to the security bracket using the special locking key wrench. All the screws required for the attachment of the security bracket, the IV pole clamp, and the turning and locking of the IV pole clamp onto the IV pole are secured using the special locking key wrench.

Should the security bracket need to be removed for cleaning (or other purpose), to resecure to the device, position the IV pole clamp over the three threaded standoff screw supports on the security bracket at the back of the MOD® device.

Once the MOD® device is programmed and the MOD® assembly unit is ready to attach to the IV pole, align the clamp to the IV pole with the rubber clamp lining support touching the IV pole. Screw the clamp onto the pole using the special locking key wrench. To secure and lock the clamp, tighten the special locking screw on the posterior portion of the clamp guide that prevents the main support clamp from unlocking. The MOD® device can also be programmed while attached to the IV pole. Retain the specialized locking key wrench in a secure location to prevent access by unauthorized personnel.

# Operating the MOD®

Note: A copy of these Instructions for Use can also be found at www.avancen.com.

## Connecting to the MOD® Device

To access information on a device or devices, to program a new patient on to a device, to modify or reload a prescription, to dispense or to discharge a patient from a MOD® device, use the following connections steps:

1. Click on the MOD® portal (or icon as labeled by your facility) located on the computer screen
2. Enter your institution ID/password to access the MOD® Program. This is typically the same ID/password that you use to gain access to the institution's computer system or network. Your password must have been set up by the System Administrator to allow this access to the MOD® programming.
3. Press the on/off button in on the rear of the MOD® device to turn on the device. The Wi-Fi light will glow red, then turn blue which indicates that the MOD® device has associated with the network server.
4. Click on the "Connect" button located on the upper left side of the screen,
5. After you click "Connect", a three digit number (shown below) will appear that is randomly generated by the system.

## Programming the MOD® Device for a New Patient

1. Press the center logo (the "Dancing Man" ) on the device front panel (you will hear a tone) and immediately enter the three digit number shown on the screen by pressing each numeric button in sequence on the MOD® device keypad to load the 3 digit code to the device. **NOTE: IF THE SCREEN CODE INDICATES ANY NUMBER THAT ENDS WITH 10 YOU MUST ENTER EACH DIGIT SEPARATELY. EXAMPLE: 810 WOULD BE ENTERED BY PRESSING THE 8 BUTTON, THEN THE 1 BUTTON, THEN THE 0 BUTTON; NOT THE 8 AND 10 BUTTON.** The Wi-Fi symbol on the front panel will turn green and you will hear a "Bing" tone confirming the connection to the wireless network. The device is now connected and ready for programming.
2. Click "Next"
3. Click the "New Patient" icon.
4. The device will start beeping and the green READY light will start to blink.
5. Hold the patient wristband or wrist wrap steadily over the space between the MOD center logo and the Wi-Fi indicator light while the device is active (light is blinking). DO NOT WAVE OR MOVE THE WRISTBAND/WRISTWRAP WHILE IT IS BEING READ (KEEP IT STEADY OVER INDICATED LOCATION). The device will give an audible chime when the wristband is read. If the wristband is NOT properly read, the device will give two "bong" sounds and will stop the sequence. Click on NEXT screen button. The screen will display a message in red **No valid wristband found. Try Again**.
6. Click Try Again. The screen code will give a three digit code to enter. Follow instructions above. Canceling the operation will take you to an ERROR CODE screen and you must restart the sequence from the beginning.
7. Once the wristband is recognized, press "Next".
8. Enter the patient order information (actual screens/entry steps may vary based on your institution's level of programming/set-up):
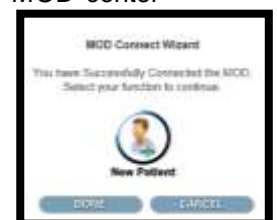
a. Patient ID: this is the number your institution uses to identify the specific patient. This field can be any combination of any letters or numbers up to a maximum of 16 characters. This field CANNOT be left blank.

b. Order number: if your institution uses an order number, it will be entered here up to a maximum of 16 letters or numbers; if not you may enter a room number or some other alpha numeric value such as the room number followed by three letters of the patient's last name, per your facility's policy. This field CAN be left blank.

c. Drug name: click on the dropdown menu to select the proper drug name that matches the patient order. The choices available will match your specific institution's formulary.

d. Dose: click on the dropdown menu to select the proper dose that matches the patient order.

e. First dispense: this may be a NOW or loading dose or given at a later time. Use the dropdown list to select the first dispense time that matches the patient order.

f. Then Dispense: This is the dosing or lockout interval prescribed between subsequent medication doses. Choose the proper dosing interval from the dropdown menu.

## Verification Screen

After entering your patient's information and pressing "done", the next screen asks you to verify that you correctly entered the information.

1. Per your institution's policy, you may be required to utilize another nurse or clinician to confirm the entries.
2. At the end of the enter order information screen, you will see three action buttons located at the bottom of the screen: Previous, Next, and Cancel.
3. If all the order information is correct, click the Next button to complete the MOD order information and the device lid will automatically open and you will advance to the final screen.
4. If you click Cancel, an ERROR screen will appear and you will be prompted to restart the set up process by clicking DONE
5. If you click Previous, the order information screen refreshes and you are returned to the top of the original order information screen to correctly re-enter all information

## Successful Configuration Screen

This screen indicates that you have successfully set up a new patient on the device. Click on "Finish" to complete the task. If a "now" or loading dose has been ordered for this patient, the green ready light on the front panel of the device will illuminate and the device is now ready to deliver the first prescribed dose.

## Loading the Medication Tray

Observe the following guidelines carefully when loading the Medication Tray. Any deviation from these procedure steps can cause the Medication Tray to jam in the MOD® device and may render the device unusable.

Follow these guidelines when loading medication trays into the device:

1. The medication trays are clear. Use caution to make sure that you are not loading one medication tray on top of an existing empty tray that is remaining in the device.
2. Slip the tray groove UNDER the recessed tray tab or "tongue" on the dispenser wheel. Once secured, you should observe that the tray is located such that each tray post (a round depression in the outer rim of each tray, and there are 4 per tray) is precisely located over a depression or small round well in the dispenser wheel.  If this is NOT THE CASE, the tray is improperly loaded.
3. Push each of the 4 round tray posts securely into the round depressed areas on the dispenser wheel. They must be pressed firmly into place but should go in evenly and easily. **If you experience any problems with a smooth locking into each depression, you may have a damaged tray and it must NOT be used**.
4. Once the tray is secure, slowly remove the adhesive cover to expose the medication. It is helpful to place 2 fingers on the tray to prevent it from rising up from the depressions in the wheel. Once again, push the round tray posts into the wheel a second time…they may have come loose during removal of the tray seal.
5. **NEVER** close the lid while the adhesive cover is on the medication tray – the patient cannot obtain the medication AND the dispenser wheel will jam.
6. Close the lid and press it down firmly to make sure it is locked in place.
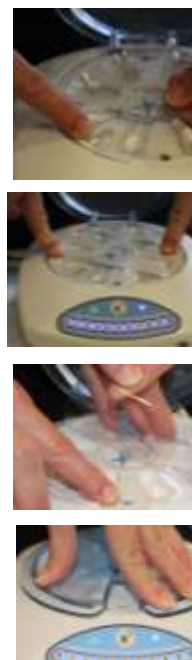
## Delivering the MOD® device for Patient Use

After programming the New Patient information into the device, take the device to the patient's room if it is not already at the patient's bedside.  Make sure to bring the RFID wristband or wristwrap to the room with you. **NOTE: Do not attach the wristband or wristwrap to the patient prior to programming as this may cause the patient discomfort.**

- Place the IV pole holding the device within easy reach of the patient.  Normally, the MOD® device is attached to the pole such that it is at a convenient height for the bed or bedside chair access by the patient.
- Secure the RFID wristband to the patient's wrist, or attach the wrist wrap to an existing wristband such that the word MOD® is facing up.
- Instruct the patient on how to use the device. It is important to observe the patient taking the first dose, if appropriate.
- Should your institution decide to use the device agreement, review it with the patient and obtain their signature, per your institution's policy.

## How the patient interacts with the MOD® device

- When the first or subsequent oral doses are available to the patient, the patient will observe that the Ready light on the left front panel will illuminate green.

- The patient must enter a pain score from 0 to 10, with a value of 10 indicating a high degree of pain and a lower value (1-3) indicating a very low level of pain.

- The patient then places his/her wristband within about 1 inch from the lighted faceplate in the area between the logo and the wireless indicator light and holds it steady until recognized.

- The device will activate, the dispensing wheel will move to the right (i.e. counter clock-wise), the pill will be exposed, and the patient takes the pill from the dispensing well.

## Pain Re-assessment

The MOD® device is equipped with a very convenient feature that encourages compliance with guidelines that require pain re-assessment, typically at one hour intervals, without deliberate action by the clinician. It is important to inform the patient about re-assessment and that the device will issue a voice command at the programmed interval; however, some hearing impaired patients may not hear the voice prompt but the lights on the faceplate will gently pulse as a visual alert as well.

The re-assessment feature operates as follows:
At an interval (typically one hour AFTER the last dose the patient received), the MOD® device will issue a voice command to "Please enter your pain level now" to encourage re-assessment by the patient. Note that the volume level of the voice command can be adjusted upward or downward depending on the patient environment.

1. When prompted, the patient pushes the button that best represents their current pain level. The patient does not need to utilize his/her wristband/wristwrap as part of re-assessment.
2. The verbal and visual reminders to the patient to input a re-assessment pain score will continue every 3 minutes for 20 minutes thereafter.
3. Please note that the re-assessment feature was designed as a convenience feature for the nursing staff. It is still the responsibility of the institution's assigned staff to communicate with the patient periodically about the efficacy of their pain treatment and any issues regarding their pain.

## Patient-Comfort Features

The device is equipped with sound and lighting variable settings. To dim or brighten the lighted front panel, the nurse holds the "Dancing Man" logo on the front lighted faceplate and presses the "9" button, raising or lowering the brightness of the faceplate (maximum of four levels, from no light to bright). To turn down/turn up the volume, the nurse holds the "Dancing Man" logo on the front lighted faceplate and presses the "1" button up to four times, raising or lowering the volume (maximum of four levels, from no sound to loud).

## Additional Functions and Commands

Once a patient has been initiated on a MOD®, three other functions or commands are available to manage the patient's pain medication process.

- Reload: This command is used to reload a new tray of the previously prescribed medication to continue the patient's current pain orders.
- Dispense Now: Deliver a "now" or clinician dose in response to break-through pain if ordered
- Remove : Remove a patient from the device and discontinue therapy for that patient.

To reload a prescription, to dispense or to remove a patient from a MOD®, use the following connections steps:

1. Click on the MOD® portal (or icon as labeled by your facility) located on the computer screen
2. Enter your institution ID/password to access the MOD® Program. This is typically the same ID/password that you use to gain access to the institution's computer system or network. Your password must have been set up by the System Administrator to allow this access to the MOD® programming.
3. If the device has been turned off for any reason, press the on/off button in on the rear of the MOD® to turn on the device (most generally, the device will be "on" while at the patient's bedside). The Wi-Fi light will glow red, then turn blue which indicates that the MOD® has associated with the network server.
4. Click on the "Connect" button located on the upper left side of the screen,
5. After you click "Connect", a three digit number will appear that is randomly generated by the system.
6. Press the center logo (the "Dancing Man") on the device front panel (you will hear a tone) and immediately enter the three digit number shown on the screen by pressing each numeric button in sequence on the MOD® device keypad to load the 3 digit code to the device. **NOTE: IF THE SCREEN CODE INDICATES ANY NUMBER THAT ENDS WITH 10 YOU MUST ENTER EACH DIGIT SEPARATELY. EXAMPLE: 810 WOULD BE ENTERED BY PRESSING THE 8 BUTTON, THEN THE 1 BUTTON, THEN THE 0 BUTTON; NOT THE 8 AND 10 BUTTON.** The Wi-Fi symbol on the front panel will turn green and you will hear a "Bing" tone confirming the connection to the wireless network. The device is now connected and ready for programming.
7. Click "Next"
8. Click the action of the icon you wish to perform (modify/reload, dispense or discharge).
9. For the Reload Function, you have the option to reload an existing medication.

**Modify the Patient's Order (this option may or may not apply based on your institution's programming/set-up)**

1. Patient ID and Order Number cannot be changed during this process.
2. Drug name: if the order has changed, click on the dropdown menu to select the proper drug name that matches the patient order. The choices available will match your specific institution's formulary.
3. Dose: Click on the dropdown menu to select the proper dose that matches the patient order.
4. First dispense: this will automatically calculate for you based on the time of last dose. NOTE: IF THE CHANGE REQUIRES A NOW DOSE OR ANOTHER TIME INTERVAL, use the dropdown list to select the first dispense time that matches the patient order.
5. Then Dispense: This is the dosing or lockout interval prescribed between subsequent medication doses. Choose the proper dosing interval from the dropdown menu to match the patient's order.



**Reload an Empty Tray:**

6. Patient ID and Order Number cannot be changed during this process. No changes to the order are required.
7. Click NEXT
8. Click "Check Box to Perform Tray Reload"
9. Click NEXT and lid will open.
10. Follow instructions on Loading a Medication Tray previously discussed in this User Manual
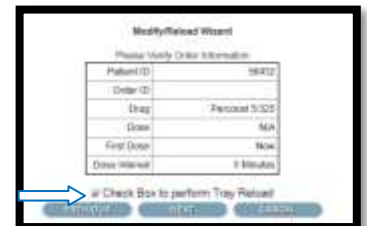


**For the Dispense function**, you will need to do the following tasks:

1. Click on the Dispense icon
2. An order verification screen will appear. This screen details last dose time.
3. Click NEXT
4. The carousel will rotate and dispense a single dose of medication
5. The time interval until next dose will automatically readjust to prescribed lockout times based on the time the medication was delivered.
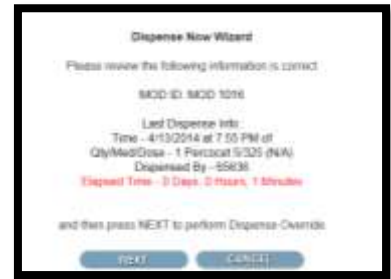
**For the Remove function**, you will need to do the following tasks:
1. Click on the Remove icon
2. Enter the number of pills remaining in the device
3. Have a second nurse verify and document the pill wastage, depending upon your institution's policies and procedures for medical reconciliation and disposal
4. The screen will display "Remove Patient Wizard". Click on the down arrow and select a number for the pills remaining.
5. In the Verifier Name field, follow the procedure dictated by your institution for the 2nd verifier (NOTE: it could be initials, a nurse ID number or some other alphanumeric established by your policy committee). Entering a value in this box is optional.
6. Click on "Next" to continue the Discharge process.
7. Lid will open. Remove tray and/or any unused pills and dispose of as per facility's medication disposal process and guidelines.

## Post Discharge Report

When Discharge has been completed, the main screen displays a Print Discharge Report option.

The Discharge Report is a multi-field report that provides one field for a series of subsequent medication events with details on the event itself (patient dose or clinician dose), the order ID, the name and dose of medication, the pain score and number of pills for a given patient's pain therapy. The results are summarized in a Discharge Summary block on the lower right side of the screen.

The pain scale portion of the report illustrates a simple bar chart that displays the pain scale on the vertical axis and the Time/Date of Doses on the horizontal access, showing the progress of pain therapy through a given therapy period. Ideally, it is desirable to see a reduction in pain levels through the therapy period as part of a successful multi-modal pain management program; however, this is dependent upon the particular patient's status and whether additional surgical or therapeutic intervention has occurred to influence the patient's level of pain. The bar chart is color-coded based on the pain score. Green color coding indicates a low pain score level of 0-3, yellow color-coding represents a moderate pain level from 4 to 7, and a red color represents a high pain score in the range of 8 to 10. An education module is suggested to orient patients to the device features and how to use them and to impress upon patients their obligation to use the device responsibly or forfeit its use. See Appendix for Sample MOD® Patient Use Checklist.

## Routine Cleaning of the MOD® Device Between Patients

Use the following cleaning procedure to clean and disinfect the MOD® device between patient use; also consult the detailed CLEANING section of the User Manual.

To open the MOD® device cover, make sure the device is turned on. Press and hold the "0" until you hear a "beep". Release the "0" and the tray will rotate and the cover will open. NOTE: This function does **NOT** work on a programmed device.

Using any of the appropriate cleaners described previously in the Cleaning Section of this User Manual, wipe down all surfaces of the device including the top cover, keypad and panel and all external surfaces, as well as the clamp mount to IV pole. Also swipe the dispensing wheel where hand contact has occurred with each dispensing well.

- Use caution to avoid any contact with electrical connections and contacts on the rear of the device.
- Wipe to clean only; do not immerse the device in liquid of any kind as immersion can cause severe damage to the device and will void its warranty.
- Clean any electrical connection areas, if soiled, with ethyl or isopropyl alcohol swabs.
- **Disposable trays and seals are not designed for re-use and should NOT be cleaned. They are single patient use only!**
- Allow wiped surfaces to dry completely prior to returning the MOD® device to use.

## MOD® Device Tips and Troubleshooting

Observe the following tips and guidelines for troubleshooting the MOD® device in clinical use.

1. The most common error that occurs in use is improper loading of the medication tray, which leads to jamming of the dispensing wheel. This impacts the patient's ability to gain access to their medication. Pay particular attention not to put a new filled tray on top of an empty tray already secured within the device, and remember to remove the tray seal to allow access to medication.
2. Do not bypass or skip the Discharge step as this will not allow the MOD® to be used on a new patient and also initiates the medication reconciliation procedures for the prior patient.
3. NEVER leave medication in an un-programmed device, or leave a MOD® device open with medication still contained within the device. It is important to allow un-interrupted time to properly discharge a patient from his/her device. The same type of caution is necessary with a MOD® device as needed with an automated medication dispensing system where all steps for secure access and control of medication must be followed.
4. If a step in any programming sequence is unsuccessful, times out or is interrupted, follow the onscreen steps to cancel or repeat the steps until it is successful.
5. When a pill slot is open, the system will not respond to commands. The open slot time delay of 45-seconds must be completed for the device to respond to commands. Allow the slot to close and then try again.
6. Remember that the on/off switch must be pushed in to the "on" position for the device to be used and programmed.

# Maintenance & Cleaning

The following guidelines for care will assure the longest life and best appearance of the MOD® device. To ensure that the device remains in good operating condition, both regular and periodic

inspections and maintenance are required. Failure to perform this maintenance may result in improper device operation.

## Maintenance

If the MOD® device shows signs of tampering or any indication of not performing to standard function during operation is not working properly, or if you are unable to open the cover or if the device is jammed, contact Avancen Customer Service to return the device. Avancen recommends that the MOD® device be checked by your facility's Biomedical Engineering Department or qualified service personnel at least once every 12 months or as indicated by institution policy. At no time should unauthorized personnel open the hard case of the MOD® device.

> **WARNING:**
> **QUALIFIED SERVICE PERSONNEL SHOULD ALWAYS INSPECT THE MOD®**
> **DEVICE IF IT HAS BEEN DROPPED OR APPEARS TO BE DAMAGED.**

### Recommended Routine Between Patient Checks

| Check | Action |
|---|---|
| **Exterior** | <ul><li>Clean as recommended in the following cleaning section.</li><li>Check for damage (i.e., cracks, dents, deformities).</li><li>Confirm that the MOD® cover is well aligned, closes without interference, and locks securely.</li><li>Verify that the MOD® IV Pole Security Holder is secure, locking, and functioning properly.</li></ul> |
| **Labels** | <ul><li>Check for readability or missing labels.</li></ul> |
| **Pain Scale Touchpad and RFID Reader** | <ul><li>Confirm that the front panel lighted numeric keypad is working properly, and that each key can be pressed and each number button functions well. The numeric keypad should be backlit at all times when the device is turned on. Do not use the device if it does not light up or if any key cannot be smoothly depressed. Also return the device if you notice that notice that multiple wristbands/wristwraps cannot be read over the logo area of the front panel, which may indicate a malfunction of the RFID reader.</li></ul> |
| **Power Supply (A/C Adapter)** | <ul><li>Inspect the A/C adapter (cord and power supply) for damage, cuts, or deformities. If damaged, replace the entire unit. Try to avoid wrapping the cord around the A/C adapter as it tends to put strain on the wiring of the cable.</li></ul> |
| **Battery** | <ul><li>The MOD® device contains a non-rechargeable battery for program memory retention purposes.</li><li>Battery is not designed to be user serviceable. An audio indication to the user will be generated when the battery needs replacement, return to Avancen for service or replacement.</li></ul> |
| **Power Check/On-Off Switch** | <ul><li>Plug in the device to make sure it runs correctly.</li><li>Press the on/off button to make sure the device powers on/off correctly.</li></ul> |

# Cleaning

- The Avancen MOD® device is designed to be resistant to fluid intrusion from any direction or source, but it should never be immersed in solutions; immersing the device will void the warranty. Keep the surface clean, dry, and free of fluid spillage at all times. Do not use the MOD® device in the shower, sauna, or steam bath and do not position the MOD® device where it could accidentally be dropped into a container of fluid (e.g. basin, tub, or toilet.)

- To prevent electrical hazards, unplug the MOD® device and its A/C adapter before cleaning.

- Only MOD® device external parts should be cleaned/disinfected, including the medication tray dispense wheel. Clean the MOD® device after each use. DO NOT spray the cleaning solution directly onto the device. Use a wipe-down procedure for cleaning. DO NOT spray a cleaning solution into the A/C adapter receptacle. When cleaning, handle the front touchpad and RFID sensor area with special care. **Do not clean the device with any corrosive material, in a highly oxidative environment, or with any cleaner having a highly acidic PH.**

- Do not clean, disinfect, or sterilize any part of the MOD® device by autoclaving. This may damage the device and will void the warranty. Disinfect MOD® device external parts only, using approved cleansers or disinfectants (hand wipe only).

- The MOD® device is classified as a non-critical item since it comes in contact with intact skin. If the MOD® device is soiled with organic matter such as blood or body fluids, clean it promptly with a soap solution to remove organic matter.

- Clean the MOD® device security holder, and IV pole clamp with a soft, slightly damp cloth, using one of the following institution disinfectants. Follow the commercial product directions for dilution and proper usage:

- 

| Approved Cleansers |
| --- |
| Ethyl or isopropyl alcohol (70-90% V/V concentration) |
| A solution of up to a maximum of 10% sodium hypochlorite (V/V) in water |
| Chloride based cleaners |
| Soap solution (to remove visible or known organic matter) |
| Hydrogen peroxide 3% (V/V) |

- Clean any electrical connection areas if soiled with ethyl or isopropyl alcohol swabs. NOTE: Before cleaning any electrical connection area, unplug the unit from the power source. Never clean a power supply area that is active (plugged into an electrical outlet)

- Remove any excess cleaning solution with a dry swab or clean cloth. Before using the MOD® device again, allow several minutes for the cleaning solution to evaporate from the surface.

- For cleaning by service personnel, the MOD® device should be unprogrammed and without a medication tray within the device. To open the cover of an unprogrammed MOD®, push and hold zero on the pain scale until a tone is heard. Release zero at tone. Tray will rotate and lid will open.

- Do not use any abrasives or hard or pointed objects to clean the device.

**WARNING:**
**SENSOR TOUCHPAD SURFACES ARE FRAGILE. NEVER USE FORCE ON SENSOR SURFACES DURING CLEANING OR USE.**

**CAUTION! THE FOLLOWING CHEMICAL DISINFECTANTS ARE <u>NOT</u> RECOMMENDED FOR ROUTINE CLEANING OF THE MOD® AND WILL VOID THE WARRANTY.**

| |
|---|
| Phenolic disinfectants (Daily use may leave skin-irritating residue on the device.) |
| Glutaraldehyde and other aldehyde-based cleaners |
| Iodophor cleaners |
| Note: No organic solvents should be used for cleaning other than those noted in the approved list of cleansers. |
| Any disinfectant containing quaternary ammonium compounds |

# MOD® Disposal

Dispose of the MOD® device and MOD® disposable accessories according to all applicable regulations. The MOD® medication disposable trays may be disposed of as nontoxic waste. However, any unused medications must be disposed of according to the specific policies and procedures of your institution. Do not dispose of the device without first contacting Avancen Customer Service.

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# Appendix

**Radio Frequency Identification** technology is part of the MOD® wireless system for identification and validation of the correct patient assigned to the device and nurse operator of the device. The MOD® device contains an RFID reader platform that is activated when the patient or nurse presses either the pain scale or the Avancen logo depending upon the task anticipated. This activates the RFID reader. The reader is a low-power 13.56 MHz module with an on-board antenna. RFID chips/circuitry is incorporated into each wristband/wristwrap. Use of this technology does not interfere with any other device or radio frequency technology such as RFID for device tracking.

Passive RFID tags are present in the patient wristband/wristwrap and have no internal power source. The range for reading the RFID tag is within 1 inch of the reader, which precludes any significant electromagnetic interference (EMI) from other systems and to other systems.

## Warranty

Avancen MOD Corporation ("Manufacturer", also referred to as Avancen herein) warrants all MOD® devices, disposables, and accessory products ("Product") to be free of defects in material and workmanship under normal use if used in accordance with this User Guide, subject to the following conditions:

- The duration of the Avancen MOD Corporation warranty is limited to one (1) year from the date of sale or the initial lease to the procurer of the MOD® devices, including batteries and accessories. Warranty shall be determined to commence upon initial delivery of the device to the facility. THERE ARE NO OTHER WARRANTIES IMPLIED OR EXPRESSED.

- There are no warranties on disposable products, but any quality issues or complaints with disposables shall be remedied by Avancen MOD Corporation solely with replacement of disposables in like kind and quantity upon notification within 90-days of receipt. Disposables for purpose of the warranty shall include medication trays and seals, and wristbands.

- Software and the media upon which it is provided to the user (if applicable) is only subject to replacement up to and within 90-days from period of receipt.

- No other express warranties are made with respect to any Product. All implied warranties, including warranties of merchantability and fitness for a particular purpose, are limited to the warranty period set forth above. The Product can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Product for any particular medical treatment or patient. This is an Rx only product in that its's use is governed by and utilized solely a licensed prescribed in a controlled healthcare setting.

- This warranty is not transferable and applies only to the original purchaser or leaseholder of the Product.

- Avancen MOD Corporation, at its sole obligation under this warranty, will replace or repair at its option any Product that does not conform to the term of this warranty. Products may be repaired or replaced with new or with refurbished items at the discretion of Avancen MOD Corporation. This limited warranty does not cover defects in appearance, cosmetic, or normal wear and tear, or decorative items, including any non-operative parts. Under NO circumstances will Avancen MOD Corporation be liable for any incidental or consequential damages under this warranty or any implied warranties. These remedies are the customer's exclusive remedies for breach of warranty. This limited warranty only extends to customers who are initial purchasers and who purchase the Product in the United States of America. If

product is sold, resold, or leased to a second party the warranty is not transferable under any circumstances.

- The warranty is void and Avancen MOD Corporation will not be responsible for damage resulting from any (i) deviation of the instructions for use  as printed in the Avancen MOD Corporation Instructions for Use or on any packaging, labels, or other literature provided with a Product; (ii) installation of a Product in a manner which is inconsistent with Avancen MOD Corporation's written instructions; including those contained in this user manual; (iii) alteration or modification of a Product; (iv) misuse; (v) neglect, (vi) abuse, (vii) accident, (viii) normal wear and tear, (ix) improper cleaning; (x) improper storage; (xi) environmental conditions, including excessive temperature or humidity; (xii) service by anyone other than authorized Avancen MOD Corporation repair personnel; (xiii) other improper application, installation, or operation of the Product; (xiv) use of non-approved accessories; or (xv) defects or malfunctions of which Avancen MOD Corporation is not advised within ten (10) days of the expiration of the limited warranty period.

- This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights, which may vary from state to state. **No person, representative, agent, or employee of the manufacturer is authorized by Avancen MOD Corporation to modify or add to this limited warranty.**

## Warranty Procedure

Notice of the claimed defect must be made in writing or by telephone to Avancen Customer Service. Notice to the manufacturer must include model and serial number, and a description of the claimed defect in sufficient detail to allow the manufacturer to determine and facilitate any repairs that may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PRODUCT and confirmed with issuance of a Return Authorization Number. When authorized, the Product must be properly and carefully packaged and returned to the manufacturer. Any loss or damage during shipment is at the risk of the sender. Contact Avancen Customer Service at 1-800-607-1230 or via the website at www.avancen.com for Terms and Conditions of Sale.

# MOD® System Specifications

| SPECIFICATION | PARAMETERS |
|---|---|
| **Dimensions** | ▪ 7.5" W x 8" L x 2.75" H |
| **Weight** | ▪ 2.5 lbs. |
| **Case Material** | ▪ Flame retardant, self-extinguishing, non-toxic cover made of ABS (acrylonitrile butadiene styrene) medical-grade plastic. The Pain Scale and overlay are from a Lexan® printed polycarbonate film. |
| **Integrated Battery** | ▪ Lithium-Manganese Dioxide Battery (Li/MnO2): 9.0 V nominal<br>▪<br>▪ Life Rating: Audio indication to user when battery requires replacement<br>▪ 3 volt lithium memory backup battery |
| **A/C Power Supply** | ▪ CUI Inc. Medical Power Supply Adapter Model: EMMA 120250-P1 1P-1C-C1<br>▪ Plugs into a standard wall outlet<br>▪ 120V A/C Adapter<br>▪ Input: 100V-240V-50-60Hz/0.45A<br>▪ Output: 12 VDC = 2.5A |
| **Special Operating Environments** | ▪ Use of the MOD® device is not compatible with high magnetic field environments (such as MRI suites), x-ray field exposure, or use in hyperbaric chambers designed for hyperbaric therapy. Use of the MOD® device has not been tested or verified to any known aviation or flight testing specifications, either civilian or military |
| **Medication Tray Insert** | ▪ Disposable, single-use only, polycarbonate plastic<br>▪ 8 medication dose slots |
| **Fixed Settings from Factory** | ▪ RFID reader ON time interval: 7 seconds<br>▪ RFID reader range: 1 inch<br>▪ Medication dose access time: 45 seconds to remove dose |
| **Delivery Time, Range, and Intervals** | ▪ Initial or First Dispense Time Intervals: *Now* or from 15m, 30m, 45m, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 6 hr or as determined by the individual institution<br>▪ Subsequent Dispense Time Intervals, Lockout Intervals: 2 hr, 3 hr, 4 hr, 6 hr, 8 hr for general use, or as set by the individual institution |
| **Data Fixed Storage from Factory Settings** | ▪ Programmed data is automatically moved from the device into the MOD® Database for manual entry into the hospital or institution's electronic EMR/patient record. |

| SPECIFICATION | PARAMETERS |
| --- | --- |
| **Signals and Alerts** | ▪ READY Signal Light: **GREEN** LED signal light turns on when the MOD® is ready to accept RFID activation and dispense a dose. READY light blinks when the MOD® is ready to read a RFID Wristband. READY Signal Light turns **RED** when the medication tray is empty.<br>▪ WIRELESS CONNECTION Alert Light: Alert light will briefly glow **RED** when the unit is first powered on and **BLUE** when it connects establishes a connection to the institution's wireless network. Light turns **GREEN** when the device is activated on the network during programming.<br>▪ Audible programming alerts: Clinicians are alerted to successful attempts steps when entering information with "positive" tones and when incorrectly entered, "negative" tones. Negative tones indicate that the programming sequence cannot be advanced until the specific issue is remedied<br>▪ Audible and visual alerts: Patients will hear a slight beeping sound when they press their corresponding pain scale which signals that the RFID sensor/reader is engaged. When entering pain scale reassessments, the lights on the faceplate will gently pulse and an audible message will be emitted from the device ("Please enter your pain level now") will be heard every three minutes for up to 20 minutes.<br>▪ Variable lighting and sound levels (four variable levels). Nurse holds "Dancing Man" logo and presses either "9" (to adjust light) or "1" (to adjust sound) |
| | ▪ |
| **Tamper Resistant Features** | ▪ Auto Locking: MOD® device cover locks upon closure and can only be reopened by authorized personnel accessing the device's software through the institution's wireless network.<br>▪ IV Pole MOD® Security Holder with heavy-duty proprietary lock. |
| **Connection to Programming Device** | ▪ Device is wireless and connects via Wi-Fi to institution's wireless network |
| **Operating Conditions** | ▪ 10º C to +40º C (50º F to +104º F) temperature<br>▪ 20% to 75% relative humidity (non-condensing)<br>▪ 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure |
| **Storage Conditions** | ▪ 10º C to +40º C (50º F to +104º F) temperature<br>▪ 20% to 75% relative humidity (non-condensing)<br>▪ 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure |
| **RFID Tags** | ▪ Avancen RFID wristband or RFID wristwrap<br>▪ Patient RFID Wristband coding is unique per patient. Low-power 13.56 MHz module with an on-board antenna |

| SPECIFICATION | PARAMETERS |
|---|---|
| **Enterprise System** | ▪ For detailed enterprise system hardware and platform requirements, please reference the MOD® Enterprise System document in the Appendix. |
| **Environmental Conditions for Transport** | ▪ There are no special environmental conditions for transport of the MOD® device. |

## Sample Patient MOD® Use Checklist

### MOD® PATIENT USE CHECKLIST

**Patient Education**

_____ The patient has received instruction in MOD® device use, including
- The attachment of the wristband and instructions in how to use the band
- A demonstration of how to use the wristband
- The time interval concept between allowed doses
- A reminder to call the nurse if assistance is needed
- How to obtain the medication at the prescribed interval
- How to enter a pain score into the device
- How to enter a pain score reassessment into the device

_____ The patient was given the Patient Guide on MOD® device use and the pain scale with reinforcement of the education to keep at the bedside.

**Patient Responsibility**

**The patient is reminded of these rules:**

_____ The device is the responsibility of the patient and only the patient.

_____ The patient agrees to call the nurse if the device does not appear to be working correctly.

_____ The patient agrees to call the nurse if the red empty tray light comes on.

_____ The patient agrees to request the medication from the device only when needed.

_____ The patient agrees to take the pill when requested – they will not save it to take home or for other uses.

_____ The patient will obtain the medication only for his/her use. The patient should not and will not provide the medication to any other party.

_____ If the nurse suspects the patient is irresponsible with the device, the device will be removed by the nurse and the physician will be notified.

_____ The patient verbally agrees that all of these rules for MOD® device use have been understood and that the patient agrees to abide by these rules.


_____          _____/_____
Patient Name/Signature:                                Date/Time:


_____          _____/_____
Nurse Instructor:                                      Date/Time:

## Troubleshooting

Most operational issues with the MOD® device can be resolved by verifying that the MOD® is adequately powered. To verify that the MOD® device is ON, attach the MOD® device to its A/C adapter and plug the unit into an A/C outlet, and press the on/off button in to turn on the device. The front panel, logo, buttons and wireless icon should illuminate when on. Refer to the troubleshooting table below for common issues and corrective actions.

| ISSUE | CORRECTIVE ACTION |
|---|---|
| **The MOD® device does not turn on or activate** | Attach the MOD® device to its A/C adapter and plug the unit into an A/C outlet. Ensure the on/off switch is pressed in to power on/off the device.<br><br>If the device has never been programmed or is not programmed begin by making sure the MOD® device can be accessed and programmed through the web browser and that it can be activated when selected.<br><br>To communicate with any particular MOD® device, a three-digit code is randomly generated by the software. The logo button and three-digit code must be entered and a confirming tone heard to insure that a particular MOD® device can be connected and receives programming.<br><br>The wireless icon must turn from blue to green, indicating it is connected for purposes of programming. |
| **The MOD® device does not respond to RFID activator (wristwrap or wristband)** | Verify that you are using the correct RFID wristband/wristwrap programmed for the MOD® device in question. |
| **Green READY light does not illuminate when the dispense time interval is reached** | Connect the device to your network and MOD® program screen and use the Modify/Reload pathway to check the current program within the device for the correct lockout interval. |
| **The MOD® device cover will not lock when it is closed** | Repeat the process by firmly pressing down on the cover into the lock a second time. You will hear a "click" when the device cover has locked. To confirm, gently lift up from underneath lid to check. |
| **Dispenser wheel will not rotate** | The disposable tray may not be seated properly, causing the wheel to "jam." Remove the device from service and contact Avancen. |

# MOD® Enterprise System

This document provides hospital IT or technical staff an overview of the system/hardware requirements for the MOD® 2.0 Enterprise System.

**Overview**
The MOD® 2.0 Enterprise System consists of:
- One or more MOD® wireless Wi-Fi devices

- Microsoft Server 2008+ hosted server

- Hospital provided Wi-Fi network

- Administrative PC for configuring MOD® devices and Enterprise settings

- MOD® Programming Clients

**Server Requirements**
The MOD® 2.0 Server Requirements are as follows:
- Hardware with Microsoft Server 2008+

- Microsoft SQL Server Database (2008+ Express or full version)

- .NET Framework 4.5

- IIS Web Server

- Fixed IP Address (or DNS entry), accessible via Wi-Fi network

- Service Account Logon (Active Directory Account) for MOD® Enterprise Windows

  Service, IIS, and Microsoft SQL Server

- Open TCP port 11000 (accessible via Wi-Fi network)

Server(s) meeting minimum hardware specifications required for running MS Server 2008+ with SQL and IIS are sufficient.

**MOD® 2.0 Wi-Fi Requirements**
The MOD® 2.0 Wi-Fi Requirements are as follows:
- MOD® devices can utilize DHCP or fixed IP addresses
- MOD® devices must be able to access the IP address of the MOD® 2.0 Enterprise Server and create a TCP connection on TCP port 11000. Firewalls and routers may need to be configured accordingly.
- Supported Security

  ➢ WEP

  ➢ WPA

  ➢ WPA2/Personal

  ➢ WPA2/Enterprise (802.x), AES/PEAP MSCHAP v2, integrating into AD/RADIUS

**Administrative PC Requirements**
The MOD® 2.0 Administrative PC hosts the applications for configuring MOD® devices and/or Enterprise level settings. The applications can be hosted on any Windows 7+ Pro device with

access to the MOD® Enterprise Server.  The applications can also be hosted on the Enterprise Server if physical access to the server USB ports is feasible.

The MOD® Configuration application is used to setup the MOD® device on the Wi-Fi network. ***This application requires access to a USB port.***

## MOD® Programming Clients

MOD® Programming is accomplished via the web server provided by the MOD® 2.0 Enterprise Server. Clients must be able to access the IP address/port of the web server on the MOD® 2.0 Enterprise Server.

While any device/web browser can access the web server, the website is currently optimized for screens with resolutions of 1280x800 or greater, typical of 10" tablets, and most PCs and Laptops.

## Network Access and Security

The MOD® 2.0 Enterprise System effectively runs as a closed system on the hospital provided Wi-Fi/LAN networks. Access is restricted accordingly to hospital policy, including physical access control and Active Directory/LDAP group policy management. Typically, hospitals will create a LDAP security group to control access to the MOD® Enterprise System website.

Avancen personnel do not require external access to the system. Any maintenance, upgrade, or diagnostic procedures will be performed on-site with assistance from hospital IT staff as required.

## Resource Utilization – Network Loading

## MOD® Devices

Each MOD® device is continuously connected to the Wi-Fi network. However, the MOD® devices only send traffic over the Wi-Fi/LAN network to the server on a periodic basis. Packets of less than 512 bytes are sent once per minute for status reports and upon patient assignment, discharge, medication dispense, and pain reassessment. On average, each MOD® device will utilize less than 32K bytes per hour of network bandwidth.

## MOD® Programming Clients

Each MOD® programming client, typically a nurse workstation or tablet, will utilize network bandwidth each time a MOD® device is programmed, discharged, modified, reloaded, or dose now dispense issued. These events typically happen less than 4-5 times per shift per MOD® device.

The MOD® client web pages are HTML with small graphics files. The pages do not contain any video or other bandwidth intensive content. Therefore Avancen does not anticipate MDO client web traffic to have any significant impact on network loading.

## Resource Utilization – Database

The recommended initial sizing for the MOD® Enterprise SQL Server database is 1GB. Each MOD® device generates approximately 100KB of database entries per day or 35MB per year.

## Disclaimer

All recommendations, information, and descriptive literature supplied by Avancen MOD Corporation or its agents are believed to be accurate as of the date of this User Manual, but do not constitute warranties. The information in this document has been carefully examined and is believed to be entirely accurate. However, no responsibility is assumed for inaccuracies. Furthermore, Avancen MOD Corporation reserves the right to make changes to any products herein to improve use, function, or design. Avancen MOD Corporation does not assume any liability arising out of the application or use of any product or circuit described herein; neither does it cover any license under its patent rights nor the rights of others.

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## Patents and Copyrights

The MOD$^®$ and MOD$^®$ accessories have extensive patent protection. US Patent Numbers 7,044,302; D604,835S; 7,661,532; and 7,743,92 have been issued and other US and foreign patents are pending.

The MOD$^®$ programming software and all MOD$^®$ documentation is fully copyrighted.

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