



MOD[®] USER GUIDE



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



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Covered by U.S. Patents 7,044,302; D604,835S; 7,661,532; 7,743,923
Other U.S. and Foreign Patents Pending

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Trademarks:

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of Avancen MOD Corporation

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Classification and Approvals

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



WITH RESPECT TO ELECTRIC SHOCK, FIRE
AND MECHANICAL HAZARDS ONLY
IN ACCORDANCE WITH UL60601-1/CAN/CSA C22.2 NO. 601.1
70TK

MET Laboratories Inc. has evaluated Medication on Demand (**MOD**[®]) with respect to UL 60601-1 and CSA C22.2 No. 601.1 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, 510k-exempt, manufactured in accordance with selected 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

This User Guide contains important product information, instructions for safe use and operation. PLEASE SAVE THESE INSTRUCTIONS. The User Guide is available through the Avancen website, www.avancen.com.

IMPORTANT

Health care professionals should read this entire User Guide before operating or deploying 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 this User Guide or about safe 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[®] unit are on the back of the unit and the serial number is easily visible in the center of the clear plastic cover.

Safe and Intended Use Instructions

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. 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 access and electronically recording patient pain levels on a standard pain scale. MOD[®] is not a substitute for monitoring of patient welfare. The purpose of MOD[®] is to support the delivery of PRN medications in a healthcare setting. Do not use MOD[®] for any purpose that deviates from its design.

Warnings

1. **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.**
2. **DO NOT USE THE MOD[®] DEVICE FOR ANY EMERGENCY OR LIFE-SUSTAINING MEDICATIONS.**
3. **USE THE MOD[®] DEVICE TO DELIVER TABLET MEDICATION FORMULAS ONLY. THE MOD[®] IS NOT DESIGNED TO DELIVER LIQUID, INJECTABLE, PATCH, OR POWDER FORMS OF MEDICATION. ATTEMPTING TO LOAD THESE SUBSTANCES WILL DAMAGE EITHER THE MOD[®] AND/OR THE MEDICATION AND WILL VOID ALL WARRANTY CLAIMS.**
4. **THE MOD[®] USE IS BY PHYSICIAN ORDER ONLY.**
5. **A HEALTHCARE PROFESSIONAL MUST VERIFY THAT THE USER IS CAPABLE OF OPERATING THE MOD[®] DEVICE AND UNDERSTANDS HOW TO USE MOD[®].**

6. USE OF MOD[®] IS NOT INTENDED AS A REPLACEMENT OR SUBSTITUTE FOR A HEALTHCARE PROFESSIONAL'S RESPONSIBILITY TO MONITOR, EVALUATE, AND ASSESS A PATIENT'S ONGOING CARE.
7. WHEN PROGRAMMING MOD[®], ENSURE THAT THE CORRECT PATIENT/USER PROFILE, MEDICATION, AND MEDICATION DISPENSE ORDER ARE BEING USED PRIOR TO STARTING MOD[®]. FAILURE TO USE THE APPROPRIATE PATIENT USER PROFILE AND MEDICATION DISPENSE ORDER COULD CAUSE SERIOUS CONSEQUENCES. DO NOT USE MOD[®] IN ANY WAY THAT IS NOT 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 TRAYS.
9. DO NOT REUSE PREVIOUSLY USED MOD[®] MEDICATION TRAYS. MOD[®] MEDICATION TRAYS ARE DESIGNED FOR SINGLE USE ONLY. DISPOSE OF TRAYS AND ANY REMAINING CONTENTS AFTER EACH USE IN ACCORDANCE WITH INTERNAL POLICIES AND PROCEDURES AND APPLICABLE REGULATIONS.
10. ALWAYS LOCK AND SECURE MOD[®] 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 APPEARS TO BE DAMAGED, IMMEDIATELY REPORT THE PROBLEM TO AVANCEN SERVICE PERSONNEL AND DISCONTINUE MOD[®] USE UNTIL THE PROBLEM CAN BE IDENTIFIED AND CORRECTED.
12. TO PREVENT ELECTRICAL HAZARDS, UNPLUG MOD[®] BEFORE CLEANING. DO NOT SPRAY CLEANSERS INTO THE CHARGER POWER CORD RECEPTACLES. DO NOT SUBMERGE MOD[®] IN ANY LIQUID.
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 GUIDE, IMMEDIATELY REPORT THE PROBLEM TO AVANCEN SERVICE PERSONNEL AND DISCONTINUE MOD[®] USE UNTIL THE PROBLEM CAN BE IDENTIFIED AND CORRECTED.
15. DO NOT USE ANY MOD[®] OR MOD[®] ACCESSORY IF ITS PACKAGING APPEARS TO BE DAMAGED OR OPENED.
16. DO NOT USE THE MOD[®] SYSTEM UNTIL YOU HAVE READ AND COMPLETELY UNDERSTAND THE INSTRUCTIONS IN THIS USER GUIDE.
17. REFERENCES IN THIS GUIDE TO SPECIFIC DRUGS AND DRUG DOSES ARE FOR ILLUSTRATION PURPOSES ONLY.

Cautions

CAUTION!

MOD[®] IS NOT INTENDED TO REPLACE TRAINED PERSONNEL IN THE SUPERVISION OF MEDICATIONS.

1. CAREFULLY READ AND FOLLOW MOD[®] SYSTEM AND PROGRAMMING INSTRUCTIONS IN THIS GUIDE. 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.

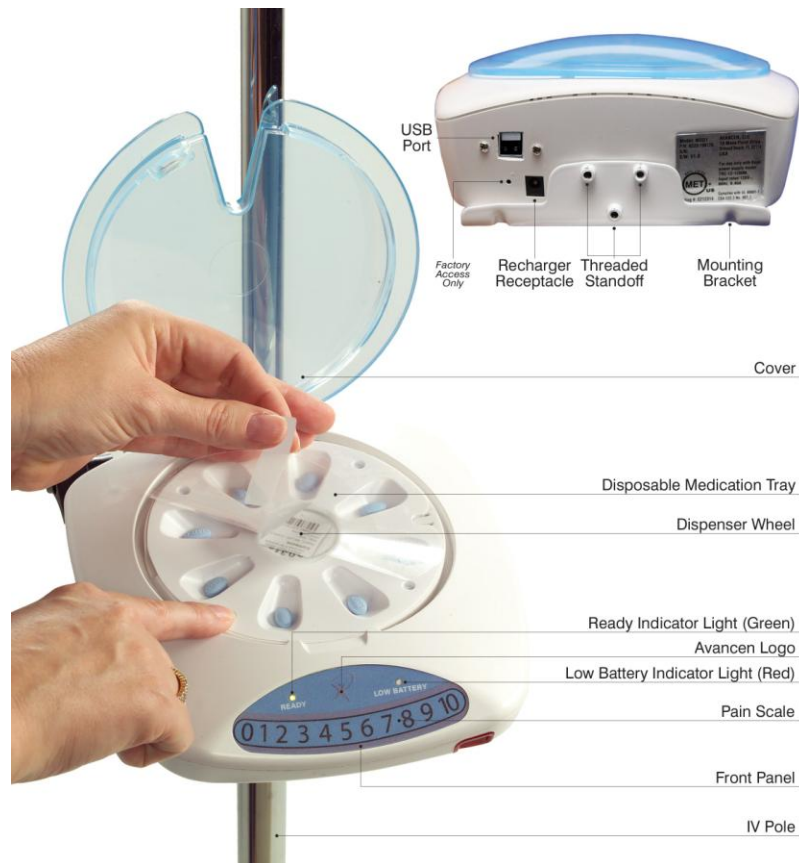
2. TO PREVENT DAMAGE TO MOD[®] EQUIPMENT, USE ONLY THE PROVIDED A/C ADAPTER WHEN CHARGING THE MOD[®].
3. DO NOT ATTEMPT TO OPEN THE MOD[®] HOUSING OR CASE. THE MOD[®] DEVICE IS CONSIDERED AN LRU (LOWEST REPLACEABLE UNIT); THEREFORE, THERE ARE NO REPAIRABLE COMPONENTS IN THE SYSTEM. WHEN THE UNIT IS NOT WORKING PROPERLY, RETURN THE UNIT TO AVANCEN. ONLY AVANCEN AUTHORIZED SERVICE PERSONNEL SHOULD REPAIR THE MOD[®] DEVICE OR ITS ACCESSORIES. AVANCEN AND ITS SUBCONTRACTORS ASSUME NO RESPONSIBILITY FOR INCIDENTS THAT OCCUR IF MOD[®] IS SERVICED BY NON-AUTHORIZED PERSONNEL.
4. KEEP MOD[®] SURFACE CLEAN, DRY, AND FREE OF FLUID SPILLAGE AT ALL TIMES.
5. THE MOD[®] DEVICE IS FLUID RESISTANT AND CAN WITHSTAND MINOR FLUID SPILLAGE. HOWEVER, IT IS NOT DESIGNED FOR TOTAL SUBMERSIONS SINCE MOISTURE BUILDUP WITHIN THE CASE COULD CAUSE DAMAGE TO THE OPERATING COMPONENTS. DO NOT PLACE MOD[®] IN THE SHOWER, BATH, OR SAUNA/STEAM BATH. DO NOT SUBMERGE MOD[®] IN WATER OR OTHER LIQUID. DO NOT POSITION MOD[®] 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 EACH PATIENT USE.
7. DO NOT CLEAN, DISINFECT, OR STERILIZE ANY PART OF MOD[®] BY AUTOCLAVING. THIS MAY DAMAGE MOD[®] AND WILL VOID THE WARRANTY.
8. DO NOT GAS STERILIZE MOD[®]. THIS MAY DAMAGE THE MOD[®] DEVICE AND WILL VOID THE WARRANTY.
9. DISINFECT MOD[®] EXTERNAL PARTS ONLY, USING APPROVED CLEANSERS OR DISINFECTANTS DESCRIBED IN THIS GUIDE.

Introduction

The MOD[®] (Medication On Demand) device is a patient-controlled drug delivery system designed to assist nursing in the safe, secure, and accurate delivery of oral tablet medications in supervised hospital, clinical, institutional, or home settings. 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. The device supports safe, secure regulatory compliance by keeping a detailed record of the date and time of medication dispensing and electronically recording patient pain levels on a numeric rating scale with each dose of medication dispensed. MOD[®] is not a substitute for the monitoring of patient welfare. Do not use MOD[®] for any purpose that deviates from its design.

MOD[®] Components

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 physician order only. A physician 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 dose) interval if desired. The pharmacy will manually fill, cover, and label a disposable medication tray for the device with eight doses of the prescribed medication. A barcode label may be adhered 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 programs MOD[®] by connecting the USB cable between the device and the programming unit (computer, PC tablet, etc.) As part of the new patient program, the nurse programs a patient RFID (Radio Frequency Identification) tagged wristband and the Nurse RFID MOD[®] Card. These are the only two items (wristband and Nurse Card) that operate the device and access MOD[®] medications. Next, the nurse enters the patient's medical identification number or code (up to nine alpha/numeric characters), the prescribed medication name, the dose and lockout time interval, and *now* dose interval if desired.



Figure 1: Nurses program the MOD[®] device using the easy-to-follow software wizard

As part of the new-patient program, the top cover is automatically opened, and the nurse loads the filled tray into the device, pulls off the tray cover, and closes the MOD[®] cover securely. Once MOD[®] is programmed and loaded, it is attached to an IV pole using a secure unique clamp system (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. Once programmed and loaded, MOD[®] is delivered to the patient bedside where it remains next to the patient for easy access and pain control.



Figure 2: MOD[®] with IV pole security holder

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

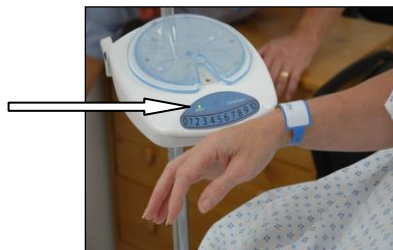


Figure 3: Green READY light signals patient when the prescribed time interval has finished and the patient can remove the prescribed medication.

To access medication, the patient touches a number on the pain scale ranging from 0 to 10 on the MOD[®] Pain Scale to document his/her current level of pain (Figure 4). This Pain Scale touch activates the MOD[®]'s internal RFID reader, and the green READY light will blink.



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 slowly swipes his/her unique RFID wristband in front the MOD[®]'s front panel where the internal RFID reader is located (Figure 5).



Figure 5: Patient slowly swipes RFID wristband over the front panel

MOD[®] identifies the RFID wristband, verifies the patient's identity, and makes available 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 MOD[®].

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. MOD[®] remains closed and inactive until the next allowed prescribed dosage time arrives. If the patient does not yet need the medication after the lockout time interval, MOD[®] remains locked with the green READY light on, ready to respond when the patient desires another dose of the medication.

Additional software programs are available for the nurse to interact with the device to obtain information or revise the program within the device. These include the Charting Log program, the Modify/Reload 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. MOD[®] DELIVERS ONLY ORAL TABLET OR CAPSULE MEDICATIONS.

Special Features

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

Integrated Rechargeable Battery

MOD[®] can be used cord free, allowing the device and the patient maximum mobility while using the device for pain management. A rechargeable battery allows MOD[®] to operate up 3-4 days between patients, a healthcare professional connects the device to its A/C adapter as described in this guide. If the LOW BATTERY light comes on during patient use, the device can be recharged at the bedside while it is still in use. The MOD can be programmed within 30 minutes of connecting the device to its A/C adapter. **SPECIAL NOTE: for optimum performance, the device should remain connected to its A/C adapter and plugged into a standard wall outlet during patient use.**

Signals and Alerts

There are two LED lights on MOD[®]'s front panel—a green light labeled READY and a red light labeled LOW BATTERY. When the green READY light is on, it shows the patient that the appropriate time interval has passed and that s/he can access the medication. When the READY light is off, the required lockout time 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 is in progress. The second light on the MOD[®] device is the LOW BATTERY alert light. This light will glow orange immediately upon connecting the A/C adapter to a wall outlet. This indicates a connection has been made. The orange light will cease after a short period of time. The LOW BATTERY light glows red when the MOD[®] battery has approximately 15% of its charge remaining. When the LOW BATTERY light is illuminated, it alerts the patient and the nurse that the MOD[®] is low on power and should be connected to its A/C adapter and plugged into a standard wall outlet. **SPECIAL NOTE: for optimum performance, the device should remain connected to its A/C adapter and plugged into a standard wall outlet during patient use.**

Integrated Pain Scale and RFID Activation



Figure 7: MOD[®] Pain Scale 0 to 10

The MOD[®] device incorporates a Pain Scale for the patient to record his/her pain level (Figure 7). Touching the Pain Scale activates the RFID reader located under the Avancen logo in the center of the MOD[®] face. The patient then holds the RFID programmed wristband in front of the MOD[®] reader. The reader recognizes the wristband and activates the dispenser wheel to turn and expose one dose of medication. The Pain Scale is for documentation only as part of the medication request process. MOD[®] records the patient's pain level input, the date, and the time of the medication dose delivery. All medication delivery data is recorded and stored in the MOD[®] memory where it can later be accessed and printed by nursing staff for easy reference to enter the data into the patient chart.

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 almost intuitively.

Tamper Proof Features

MOD[®] has a high-density, clear-plastic cover that closes and securely locks over the medication tray insert. To physically lock the MOD[®] cover, the nurse gently presses on the cover until the sturdy spring-loaded lock engages. To unlock the MOD[®] cover, the nurse must use the MOD[®] programming software or a MOD[®] Nurse Card provided with the device system. These multiple security features control access to the medication tray and make it tamper proof from unauthorized personnel and patients.

Anti-Theft and Stabilization

MOD[®] comes attached to a security bracket that in turn is locked onto a facility'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.

Radio Frequency Identification (RFID) Technology for Added Security

The patient wristband and MOD[®] Nurse Card employ radio frequency identification (RFID) technology to ensure that only the patient and the nurse can access MOD[®]. Both the wristband and the Nurse Card are programmed into the MOD[®] device as part of a new patient program. They remain as the only entry to the device until the patient is discharged from the device. Once discharged, the RFID wristband no longer operates the device.

MOD[®] 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**.

Passive RFID tags are present in the patient wristband and Nurse Card. 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 and to other systems.

Fluid Resistant

The MOD[®] medical-grade plastic body, cover, and enclosure are fluid resistant.

Ease of Tablet Delivery

The MOD[®] 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.

Detailed Recording of Medication Use

While the MOD[®] is operating and is in use by a patient, it continuously records the following in a charting log retained in its internal memory:

- 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 Pain Scale level at each medication request removal event.

- The date and time of each nurse override event to dispense unscheduled doses, frequently called “now” doses.
- The date and time for each time the cover of the device is unlocked by the nursing staff.

SPECIAL NOTE: The computer used to program the device must have the correct date/time to transfer accurate information to the MOD memory.

Patient Responsibility

The MOD[®] Drug Delivery System should be made available only to patients who are alert, oriented, and can responsibly manage the device. This patient commitment includes the requirement to report any device malfunction to the nursing or facility staff. The nursing staff should remove MOD[®] from the patient at any time the patient appears to be 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.

MOD[®] System Specifications

SPECIFICATION	PARAMETERS
Dimensions	<ul style="list-style-type: none"> ▪ 7.5” W x 8” L x 2.75” H
Weight	<ul style="list-style-type: none"> ▪ 2.5 lbs.
Case Material	<ul style="list-style-type: none"> ▪ 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	<ul style="list-style-type: none"> ▪ Nickel Metal Hydride Battery (NiMH): 6V DC with 5-hour charge time ▪ Run time: 3-4 days between charges ▪ Life Rating: 500 cycles ▪ Voltage and current protection circuit ▪ 3 volt lithium memory backup battery
A/C Power Supply	<ul style="list-style-type: none"> ▪ Kaga/Volgen Medical Power Supply Adapter Model: TRC-12-1200-M ▪ Plugs into a standard wall outlet ▪ 120V A/C Adapter ▪ Input: 100V-240V-50-60Hz/0.45A ▪ Output: 12V—1.2A ▪ Unit should be charged at the bedside during patient use ▪ Unit can remain unplugged prior to use. Requires a brief charge (5+ minutes) prior to programming.
Medication Tray Insert	<ul style="list-style-type: none"> ▪ Disposable, single-use only, polycarbonate plastic ▪ 8 medication dose slots
Fixed Settings from Factory	<ul style="list-style-type: none"> ▪ RFID reader ON time interval: 7 seconds ▪ RFID reader range: 1 inch ▪ Medication dose access time: 45 seconds to remove dose

SPECIFICATION	PARAMETERS
Delivery Time, Range, and Intervals	<ul style="list-style-type: none"> ▪ Initial or First Dispense Time Intervals: <i>Now</i> or from 15m, 30m, 45m, 1 hr, 2 hr, 3 hr, 4 hr, 5 hr, 6 hr ▪ Subsequent Dispense Time Intervals, Lockout Intervals: 30 seconds, 0.5 hr, 1 hr, 1.5 hr for demonstration only. 2 hr, 2.5 hr, 3 hr, 3.5 hr, 4 hr, 4.5 hr, 5-12 hr for general use. The MOD[®] Nurse Card can be used as a dispense <i>Now</i> card by overriding the program in the device.
Data Storage	<ul style="list-style-type: none"> ▪ Programmed data is automatically stored in MOD[®] memory. Data is not lost when the primary battery drains down or the device is unplugged. Data is transferred to the computer upon discharge and stored in the discharge computer. Memory data retention is 3 years from the initial date of manufacture.
Signals and Alerts	<ul style="list-style-type: none"> ▪ 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 or MOD[®] Nurse Card. ▪ BATTERY LOW Alert Light: Alert light will briefly glow orange when the unit is first plugged in and confirms the unit is getting adequate power to recharge the battery. Red alert light turns ON when 85% of MOD[®] charge is depleted with approximately 15% of charge remaining.
Safety Circuits and Features	<ul style="list-style-type: none"> ▪ Voltage and current protection on primary battery to prevent overcharging of the device. ▪ Automatic Device Turn-Off when the battery is near depletion for primary battery protection.
Tamper Resistant Features	<ul style="list-style-type: none"> ▪ Auto Locking: MOD[®] cover locks upon closure and can only be reopened by authorized personnel using an RFID MOD[®] Nurse Card. ▪ IV Pole MOD[®] Security Holder with heavy-duty proprietary lock.
Reset Function	<ul style="list-style-type: none"> ▪ Factory access reset button located on the backside of the device in the portal.
Connection to Programming Device	<ul style="list-style-type: none"> ▪ USB Connection
Operating Conditions	<ul style="list-style-type: none"> ▪ 10° C to +40° C (50° F to +104° F) temperature ▪ 20% to 75% relative humidity (non-condensing) ▪ 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure
Storage Conditions	<ul style="list-style-type: none"> ▪ 10° C to +40° C (50° F to +104° F) temperature ▪ 20% to 75% relative humidity (non-condensing) ▪ 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure

SPECIFICATION	PARAMETERS
RFID Tags	<ul style="list-style-type: none"> ▪ Avancen RFID wristband or wristband RFID Wrap ▪ MOD[®] Nurse Card ▪ Patient RFID Wristband coding is unique per patient. MOD[®] Nurse Card can be reused to work with multiple MOD[®] devices. ▪ Low-power 13.56 MHz module with an on-board antenna
Minimum Operating System and Hardware	<ul style="list-style-type: none"> ▪ Laptop PC or computer with 200KB of available hard drive space, USB port, and CD-ROM or DVD drive.
For MOD[®] Programming Software	<ul style="list-style-type: none"> ▪ Windows 2000, Windows 2000 Professional, Windows XP, or Windows XP Professional, Windows Vista or Windows 7 installed.
Environmental Conditions for Transport	<ul style="list-style-type: none"> ▪ There are no special environmental conditions for transport of the MOD[®] device.

Initial Setup

Each MOD[®] is manufactured to precise quality standards. However, improper handling in transit could result in damage to the device. Always inspect the MOD[®] device and its accessories for any sign of damage before using.

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[®] charging 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 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®:

- 10° C to +40° C (50° F to +104° F) temperature
- 20% to 75% relative humidity (non-condensing)
- 700hPa to 1060hPa (380mm Hg to 795 mm Hg) atmospheric pressure

Charging the Battery

If you are planning on using the MOD® device as a portable unit (without maintaining a connection to an electrical wall outlet), it is important to use the A/C adapter to fully charge its internal rechargeable battery prior to using the MOD® device for the first time. We recommend a 24-hour charge period prior to first use. **SPECIAL NOTE: for optimum performance, the device should remain connected to its A/C adapter and plugged into a standard wall outlet during patient use.**

Cleaning the MOD® Prior to First Use

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

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

Approved Cleansers
Ethyl or Isopropyl Alcohol (70-90% concentration)
Quaternary ammonium compounds
A solution of 10% bleach 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.

MOD® Starter Kit

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

- One (1) A/C adapter (battery/power cord with recharger)
- Mounting security bracket which comes already attached to the device
- IV pole clamp, mounting screws and security key

- MOD[®] User Guide (CD format)

A customized order can be arranged to provide a sufficient number of MOD[®] Nurse Cards, security locking tools, and RFID wristbands to your healthcare facility to begin operation of all MOD[®] devices procured. Additional RFID wristbands, MOD[®] Nurse Cards, and security locking tools are available 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

MOD[®] 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.

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[®] 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 can also be programmed while attached to the IV pole.

Operating the MOD[®]

Note: A copy of these operating instructions can also be found at www.avancen.com.

Preparing for Initial Programming

Before you begin programming and using MOD[®], it is important to have all the following items ready and available. You need the following:

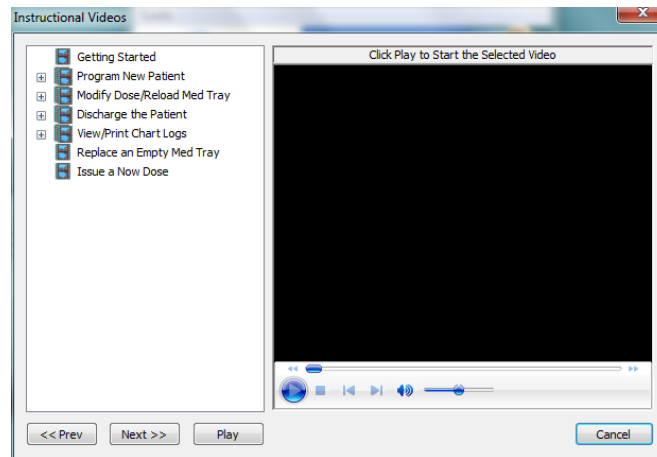
- A MOD[®] with a fully charged battery with mounting bracket and pole clamp attached
- A prefilled Medication Tray Insert
- A programming device (computer or other) with MOD[®] programming software installed and a USB cable to run from the device to your computer. NOTE: Confirm that the date/time on the computer is correct; date/time shown on the programming device will be used for recorded times.
- An IV pole to securely hold the MOD[®] device
- An Avancen patient RFID wristband (new and not previously used)
- A MOD[®] Nurse Card
- Patient's physician orders

WARNING!

PATIENT/USER PROFILE AND MEDICATION PRESCRIPTION ORDERS MUST BE ISSUED BY THE TREATING PHYSICIAN PRIOR TO STARTING MOD[®]. YOU MUST ENSURE THAT THE CORRECT PATIENT/USER PROFILE, MEDICATION, AND DISPENSE ORDER (DOCTOR'S PRESCRIPTION ORDER) ARE BEING USED. FAILURE TO USE THE APPROPRIATE PATIENT PROFILE, MEDICATION, OR DISPENSE ORDER CAN CAUSE SERIOUS CONSEQUENCES.

Instructional Videos

The MOD software comes with a complete instructional video library describing each programming action. The video library can be accessed prior to programming the device under "Tools" (see figure below). During programming, the videos can be accessed on screens with a Play Video button.



Connecting to the MOD[®]

Before you can program MOD[®], you must establish a connection between your programming device (e.g., a computer) and MOD[®] using a USB cable (supplied with the device)

Demonstration Mode: On the Application Settings screen, there is an option to select a Demonstration Mode. When the Demonstration Mode is selected, the MOD[®] programming steps can be followed for demonstration only. Going through the demonstration mode will not actually program your device; however, it can be used to review how-to steps and/or to demonstrate the MOD[®] to other healthcare professionals. Be sure the Demonstration Mode is not selected when you intend to program the MOD[®].

The following steps describe how to activate the MOD[®] device if the device **has NOT been programmed:**

1. MOD[®] will not be programmed if it is new or if a patient has been discharged from the device. Upon completion of the discharge module, the previous program is removed from the device and it is no longer programmed.

2. To activate the MOD[®] for initial programming, touch the Avancen logo in the upper center of the front faceplate for 3 seconds using your thumb. Always touch the Avancen logo using your thumb to allow your other fingers to rest on the top of the device. This prevents touching the Pain Scale and causing the green READY light to blink from accidentally activating the Pain Scale. The green READY light on the MOD[®] will blink rapidly 4 times after the connection is activated. **You do not need a MOD[®] Nurse Card if the device is not programmed.** Remove your hand from the touchpad once the green light starts to blink.



Figure 8: Touch the Avancen logo (center of faceplate) to activate the MOD[®] for initial programming

3. Select the MOD[®] Programmer (USB) icon from your Windows Start file or desktop.

Starting MOD[®] Software

To begin navigating within the MOD[®] software, you must first connect your computer via USB cable to the MOD. Select the program you wish to run (New Patient, Modify/Reload, Charting Log, or Discharge) Click on the icon that represents the action you want to complete. (Figure 9)

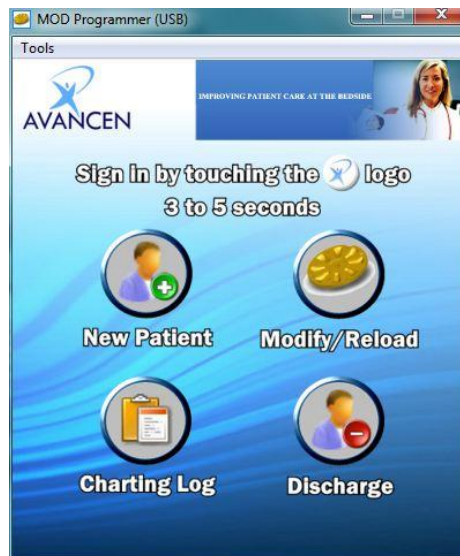


Figure 9: MOD[®] Programming Application

Programming the MOD[®] for a New Patient

The MOD[®] **New Patient Wizard** leads you through a series of steps to:

- Program the patient RFID wristband (referred to on screen as the Patient Dispense Wristband)

- Program MOD[®] Nurse Card
- Program MOD[®] with the Patient ID and Dispense (Prescription) Order Parameters
- Load MOD[®] with a prefilled medication tray insert. After the tray is inserted, remove the medication tray cover, then close and lock the MOD[®] cover.
- To complete these steps you need:
 - (1) A new, unused RFID wristband
 - (2) A MOD[®] RFID Nurse Card
 - (3) Your patient's ID (identification number) – usually the medical record number
 - (4) Your patient's Medication Dispense (Prescription) Order
 - (5) A prescribed labeled prefilled Medication Tray Insert with 8 doses of the correct medication.

Programming the Patient Dispense Wristband

The first screen that appears in the New Patient Wizard is the **Program Patient Dispense Wristband** screen (Figure 10).

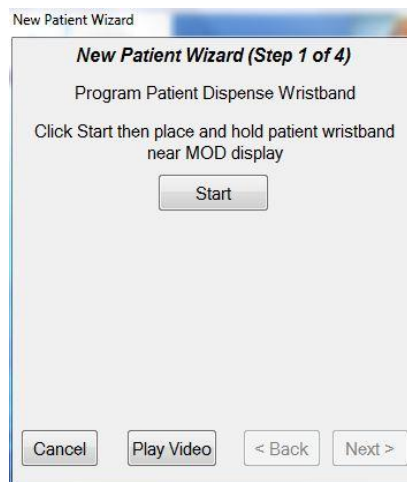


Figure 10: Program Patient Dispense Wristband screen

1. Obtain a new, unused RFID wristband. Place and hold the RFID wristband within 1 inch of the MOD[®] front panel. On the **Patient Dispense Wristband** screen, select **START** to initiate programming. When you click **START**, the green dose-READY light on the MOD[®] front panel begins to blink; this indicates that the MOD[®] is programming the RFID wristband. If the wristband is successfully programmed, the next screen appears on the programmer for the MOD[®] Nurse Card (Figure 12). Go to Programming the MOD[®] Nurse Card.
2. If the Patient Dispense Wristband HAS NOT been successfully programmed, a message will appear on the screen that says: Patient Dispense Wristband Assignment Failed. RFID Tag could not be read (Figure 11).



Figure 11: Wristband Assignment Failed

3. Repeat the **Program Patient Dispense Wristband** step by selecting **Start** again and repeat the programming process.
4. If you continue to have RFID wristband programming and assignment errors:
 - Verify that you are using an approved Avancen RFID wristband.
 - Replace the current RFID wristband that you are using with a new RFID wristband. (You may be using a damaged wristband.)
5. Repeat the Program Patient Dispense Wristband steps with the new RFID wristband.

Once the RFID wristband is successfully programmed and assigned, the Program MOD[®] Nurse Card screen will appear (Figure 12).

Programming the MOD[®] Nurse Card

The next screen that appears is the **New Patient Wizard Step 2 - Program Nurse MOD[®] Card** (Figure 12).

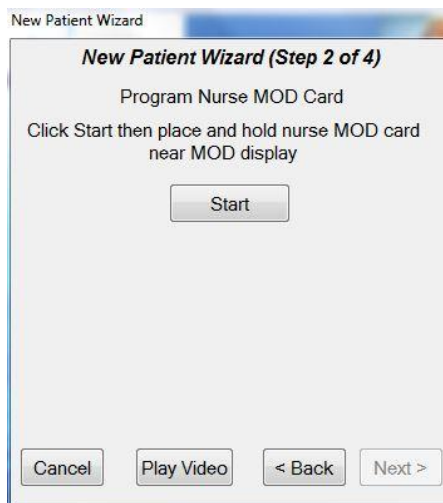


Figure 12: Program MOD[®] Nurse Card

You will program the MOD[®] Nurse Card using steps similar to those used to program the RFID wristband. To program the Nurse Card:

1. Obtain an RFID-tagged MOD[®] Nurse Card.
 - If you would like to use the same card to control more than one MOD[®] then obtain a previously assigned Nurse Card.
 - If you would like to use a different Card for every MOD[®] and patient, obtain a card that is not already assigned to a device.
2. Place and hold the MOD[®] Nurse Card within 1 inch of the MOD[®] front panel and click **Start** on the screen to initiate programming (Figure 12).
 - When you select Start, the green READY light on the front panel of the MOD[®] begins to blink. This indicates that the MOD[®] is programming the MOD[®] Nurse Card.
 - If the programming is successful, the next screen will appear which says: **New Patient Wizard (Step 3 of 4) Input Patient, Drug, and Dispense Order Information** (Figure 13). Go to Programming the Patient and Dispense Order Parameters.
3. If the MOD[®] Nurse Card HAS NOT been successfully programmed, a message will appear on the bottom of the screen which says: **Nurse MOD[®] Card Assignment Failed**. Repeat the Program Nurse MOD[®] Card steps previously noted until you can successfully program and assign the MOD[®] Nurse Card.
4. If you continue to have MOD[®] Nurse Card programming and assignment errors:
 - Verify that you are using an approved Avancen MOD[®] Nurse Card.
 - Replace the current card that you are using with a new card. (You may be using a damaged card.)
 - Repeat the Program Nurse MOD[®] Card steps with the new Nurse Card.

Once the MOD[®] Nurse Card is successfully programmed and assigned, the next programming step is to enter the patient data and dispense order data.

Programming the Patient and Dispense Order Parameters

New Patient Wizard

New Patient Wizard (Step 3 of 4)

Input Patient, Drug, and Dispense Order information. Click Next to continue.

Patient ID

Drug Name

Drug Dose

First Dispense is

Then dispense

Figure 13: Program Patient and Dispense Order Parameters screen

1. Using this screen, you will:
 - Program MOD[®] with the patient's ID Number – usually the medical record number.
 - Program MOD[®] with the patient's prescribed medication and drug dosage strength. Enter the generic drug name or select from a drop-down menu.
 - Program MOD[®] with time intervals for dispensing the patient's individual medication doses.
2. To begin programming MOD[®] on the Program Patient and Dispense Order Parameters screen.
 - Select **Patient ID** text box and enter your patient's identification code Note: this textbox accepts up to 9 alphanumeric characters.
 - Select the **Drug Name** text box and enter the generic name of the drug prescribed. Note: This textbox accepts up to 15 alphanumeric characters. Commonly used drugs may appear in the drop-down menu.
 - Select the **Drug Dose** text box and enter the prescribed dose of the drug as specified by your patient's prescribed Dispense Order. Enter the exact dose and the units provided – for example, 5 mg.
 - Select the time the first drug dose is to be available to the patient (now, in 15 minutes, etc.). Scroll the up/down arrows on the right side of the **First Dispense Is** box to select an initial dispense time. You may select an initial dispense time that is immediate (now) or from 1 minute up to 6 hours from now.
 - Select how often each additional drug dose is to be available to your patient by specifying the lockout interval as the **Then Dispense** number. Scroll the up/down arrows on the right side of the box to specify the minimum amount of time that must pass between available medication doses. You can select a lockout time interval ranging from every 2 hours up to every 12 hours (demonstration lockout periods range from 30 seconds to 1.5 hours).

Figure 14: Completed Program Patient and Dispense Order Parameters Screen

3. After you have entered the correct patient data and Dispense Order information on the screen, click **NEXT** to continue.
4. A **Dispense Order Confirmation** window will open.

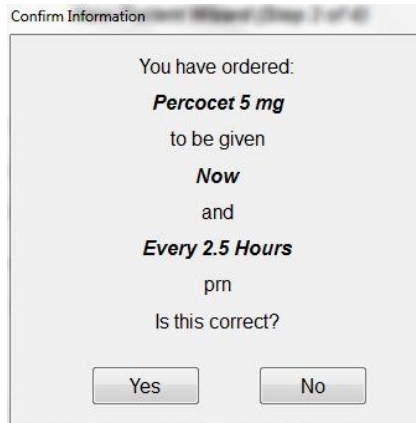


Figure 15: Dispense Order Confirmation window

5. Carefully review the dispense order information on the Confirm Information screen (Figure 15). Select **YES** if correct to proceed to the next screen.
6. If the dispense information on the screen is **INCORRECT**, point to and click **NO**. The programming wizard will return you to the data entry screen where you can re-enter the correct information.

Loading the Medication Tray Insert

1. After clicking **NEXT** on the New Patient Wizard, Step 3 of 4, the program advances to the New Patient Wizard, Step 4 of 4 (Figure 16).



Figure 16: Load Medication Tray Insert screen and confirmation screen

WARNING:

BEFORE LOADING MEDICATION INTO MOD[®], ENSURE THAT THE MEDICATION TRAY INSERT CONTAINS THE CORRECT MEDICATION AND DOSAGE STRENGTH FOR THE PATIENT ACCORDING TO THE PATIENT'S PRESCRIBED ORDER.

2. Verify that you are using the correct medication tray prescribed for your patient. See warning above.

3. Select **Unlock** on the Load Medication Tray Insert window (Figure 16). MOD[®] will physically unlock and its protective cover will open, allowing you to access the medication tray area. If the cover does not unlock, click again on **UNLOCK**. The dispenser wheel will turn to unlock. You may choose to gently place a finger under the cover to assist in raising the cover when the unlock step begins (not required). Allow the wheel to complete its turn before loading the medication tray.
4. To load the medication tray (Figure 17), slip the groove in the tray under the groove in the dispenser wheel and align the four tray projections into the holes on the dispenser wheel. Gently press down to align the medication tray properly.

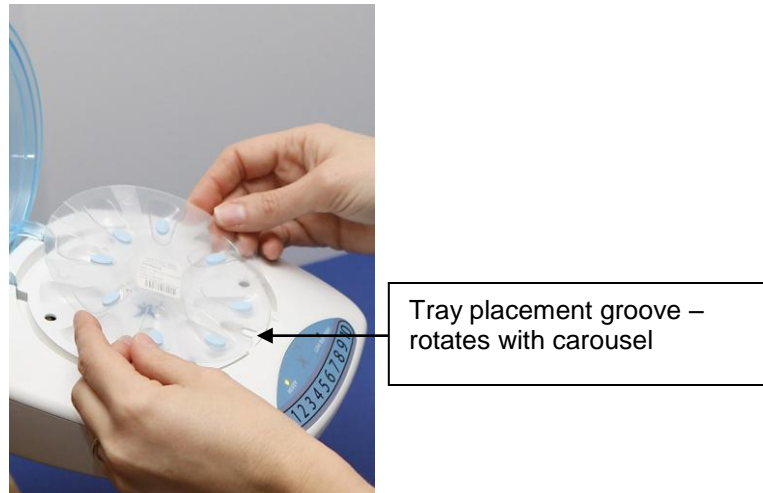


Figure 17: Loading the Medication Tray

5. Once you have installed the Medication Tray Insert, gently pull off the adhesive cover until the tray cover is removed. You may then validate the bar-coded tray to validate eight identical doses of medication if barcode validation is used in your facility (barcode validation may work without removing the cover). Close the MOD[®] cover by pressing down on it until it locks into place. When the cover is closed, you'll hear a click indicating it is locked.
6. Verify that the MOD[®] cover has indeed locked by gently lifting up on it to see if it opens. If the cover opens, press down on it again until you feel a connection, indicating that it has locked.
7. Select **FINISH** on the Step 4 of 4 screen to complete the program. This returns the screen to the main menu.

The programming process takes about two minutes to complete from Start to Finish.

Patient Usage of the MOD[®]

Activating the MOD[®]

Once MOD[®] is programmed and loaded with a patient's prescribed medication, the patient can activate the MOD[®] device and access a dose of medication any time the programmed lockout time period has passed.

A patient 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.

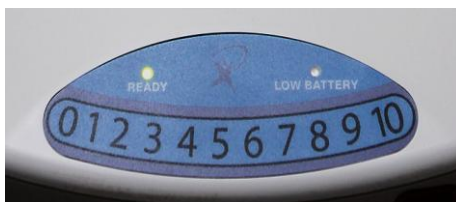


Figure 18: Pain Scale on the Face of the MOD®

To access a dose of medication, the patient must complete the following steps in this order:

1. Verify that the green READY light is on. NOTE: MOD® will allow patient access **only** when the lockout interval of time has passed as noted by the illuminated green READY light.
2. Enter a pain value ranging from 0-10 (0 = least amount of pain; 10 = greatest amount of pain) by touching the Pain Scale touchpad number that best represents the level of pain experienced (Figure 18). NOTE: The MOD® RFID reader activates when the patient enters a Pain Scale value. Upon RFID reader activation, the green READY light begins to blink.
3. While the READY light is blinking, move the RFID wristband within 1 inch of the MOD® front panel where the MOD® internal RFID reader is located. The READY light will blink for 7 seconds.
4. When a successful reading of the RFID wristband occurs, the MOD® dispenser wheel will rotate to an open position to provide access to one dose of medication. The patient removes the medication dose with the fingertip. A patient has 45 seconds to remove the medication dose. After 45 seconds, MOD® automatically closes and denies access to another dose until the programmed lockout time interval has passed.
5. If the medication dose is not removed before the MOD® device closes, the patient must contact a nurse. A nurse can manually override the MOD® program and access a single dose at any time using the preprogrammed MOD® Nurse Card. See Overriding the MOD® Dispense Program for directions.

Overriding the MOD® Dispense Program

The MOD® Nurse Card provides access to all the device programming, access to override the program to dispense a dose of medication, and the ability to open the device cover for access to the medication tray.

The need to manually override the MOD® program and immediately dispense a dose of a patient's medication may occur if the patient has an order called a "Now Dose" for a special circumstance. An example of this may be a "Now Dose" when the patient is called to physical therapy. In this scenario, the nurse may obtain the dose from MOD® for the patient instead of going to the med cart and removing a separate dose.

Using the previously programmed Nurse Card, complete the following steps:

1. Press the number 10 on the MOD® Pain Scale for 3-5 seconds until the READY light begins to blink.
2. While the READY light is blinking, place the Nurse Card within 1 inch of the MOD® faceplate. The READY light will blink for 7 seconds.
3. When you have successfully activated the MOD® with the Nurse Card, MOD® moves to an open delivery position, giving access to one dose of the patient's medication.

4. The patient (or the nurse) must remove the medication dose from the MOD[®] within 45 seconds. After 45 seconds, the MOD[®] automatically closes and reverts to its original patient Dispense Order programming. The programmed lockout time begins counting down from the time the MOD[®] device rotates to a closed position. MOD[®] records the date and time as an override dose in its internal memory and charting log. The patient cannot access another medication dose on demand until the full lockout time interval has passed.
5. If the MOD[®] Nurse Card does not activate the MOD[®] providing access to the medication dose, verify you are using a MOD[®] Nurse Card that has been programmed for the MOD[®] you are attempting to activate. Repeat the above steps beginning with the initial step of pressing 10 on the Pain Scale.

Opening the MOD[®] Cover

The MOD[®] Nurse Card allows you to open the device cover to access or change the Medication Tray Insert. When you open MOD[®], it preserves the current patient programming. The current programming will resume when you close and relock the cover. MOD[®] will record in its memory the unlock step. To load a new Medication Tray Insert without the need to change any of the programming, follow the steps described in this section. You will need a MOD[®] Nurse Card previously programmed for the MOD[®] holding the tray you need to change to complete these steps.

If a patient is discharged and the medication tray needs to be removed, connect the device to your programming device with the USB cable and follow the **Discharge** module which removes the patient program from the device. If a new tray with a different medication is being loaded into the device, you must connect MOD[®] (to a computer or other programming device using the USB cable) and use the **Modify/Reload** module to change the Patient and Dispense Order Parameters. Always dispose of any unused medications per the hospital policy for disposing of unused oral medications.

Using the MOD[®] Nurse Card, execute the following:

1. Press and hold down the number zero (0) on the MOD[®] Pain Scale for 3-5 seconds until the READY light begins to blink.
2. While the READY light is blinking, place the MOD[®] Nurse Card within 1 inch of the MOD[®] front panel. The READY light will blink for 7 seconds. You must place the card near the MOD[®] front panel within 7 seconds while the READY light is blinking for MOD[®] to open.
3. Observe the MOD[®] cover unlocking and opening as the dispenser wheel turns, giving you access to the Medication Tray Insert. Wait until the tray has turned in two directions and stopped prior to attempting to remove the tray.
4. Gently lift the current Medication Tray Insert out of the MOD[®] and replace it following the same steps used in loading the initial tray. (See **Loading the Medication Tray Insert** in the **Programming and Loading the MOD[®] for a New Patient** section of this manual.)
5. After you have properly loaded the new Medication Tray Insert into the MOD[®], remove the medication tray's disposable cover, gently close the device cover, and press on it until it locks. The MOD[®] resumes its current programmed operation. The Dispense Orders and times remain as programmed.
6. If you follow the above steps and your MOD[®] Nurse Card does not open the MOD[®], verify that you are using a MOD[®] Nurse Card that has been programmed for the MOD[®] you are attempting to open. Repeat the above steps, beginning with the initial step of pressing zero (0) on the Pain Scale.

Modifying Dispense Orders and Reloading Medication

The MOD[®] Patient Dispense Order parameters can be changed by using the MOD[®] **Modify/Reload** programming wizard. This program provides for a change in medication type, dose strength, or frequency of delivery. If the medication type or dose is changed, there is a need to reload the MOD[®] with a new Medication Tray Insert. This program includes an unlock step for the MOD[®] top cover to change trays.

First, using the USB cable, connect MOD[®] to your programming device (computer, etc.).

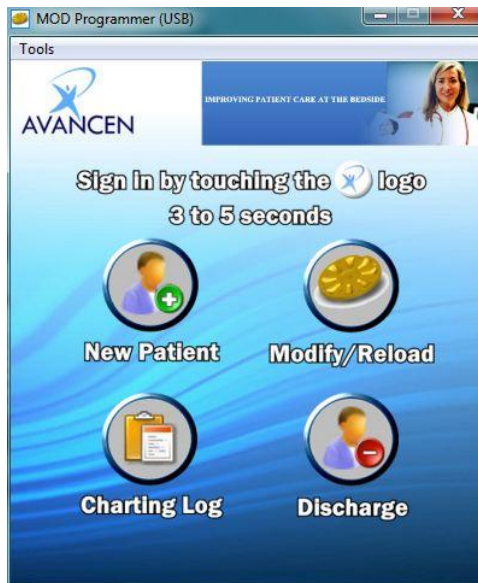


Figure 19: Main Menu: Program icons

1. Select the MOD[®] programming wizard from your Windows Start list or Desktop. Then select **Modify/Reload**. For detailed instructions, review again the section on **Connecting the MOD[®] to the Programming System**.

Figure 20: Modify/Reload Wizard: Current MOD[®] Programming, dispense order screen

2. Modify the drug and dispense information using the Modify/Reload Wizard screen as required (Figure 20). Review it carefully for accuracy. Select **NEXT** to continue.
3. The **Confirm Information** screen appears to validate the orders again.

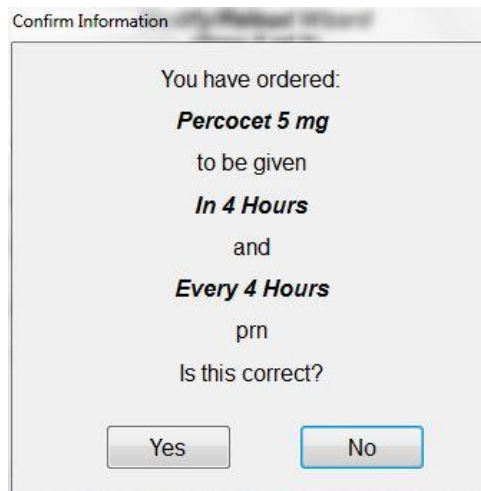


Figure 21: Dispense Confirm Information Screen.

4. Review the information on the **Confirm Information** screen (Figure 21) and verify that it is accurate.
 - If the dispense information on the screen is correct, click **YES** then **NEXT** to move to the next screen.
 - If the dispense information on the screen is incorrect, click **NO** and the screen will return to the original programming screen to correct the information.

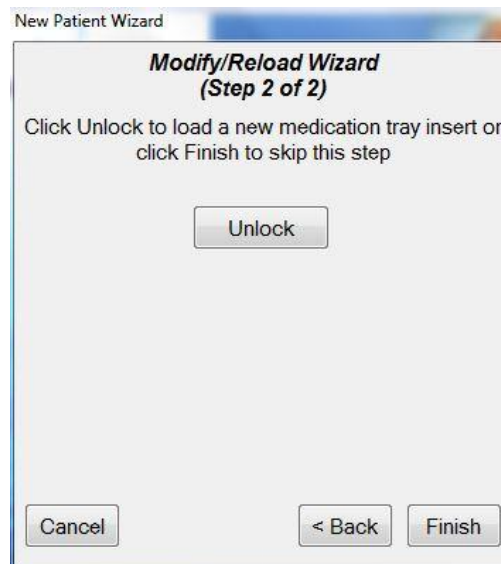


Figure 22: Modify/Reload Wizard: Reload Medication Tray by selecting Unlock.

5. Select **Unlock** on the screen and the MOD[®] cover unlocks and opens, giving you access to the Medication Tray Insert (Figure 22).

6. Gently lift the existing Medication Tray Insert out of the MOD[®] and replace it with a new tray insert following the same procedures used to load the initial tray. (See **Loading the Medication Tray Insert** in the **Programming and Loading the MOD[®] for a New Patient** section of this manual.)
7. After loading the new Medication Tray Insert, remove the medication tray cover and gently close the MOD[®] cover, and press the cover until it locks. The MOD[®] will resume operation with its new modified programming.
8. Dispose of any medications in the tray removed per hospital policy for disposing of oral medications.
9. Select **Finish** on the screen which says **Modify/Reload Wizard Step 2 of 2** (Figure 22) to return to the main menu of programming icons.

Obtaining MOD[®] Charting Logs

While MOD[®] is operating and used by a patient, it continuously records in Charting Log memory the following:

- The dates and times of patient-activated medication dispense events.
- The patient's Pain Scale level documented during each dispense event.
- The dates/times of MOD[®] programming override events using the MOD[®] Nurse Card.
- The dates/times when the MOD[®] cover is unlocked using a MOD[®] Nurse Card.

To access the **Charting Log** module, a MOD[®] Nurse Card previously programmed for the MOD[®] is needed to reconnect the MOD[®] to its programming wizard.

1. Connect the device to your computer using the USB cable.
2. Select the MOD[®] programming wizard from your Windows Start list or Desktop. Then select **Charting Log**. For detailed instructions, review again the section on **Connecting the MOD[®] to the Programming System**.
3. The next screen to appear will be the **Charting Log Wizard Step 1 of 1** of the current patient using the identification number of the patient (Figure 23).

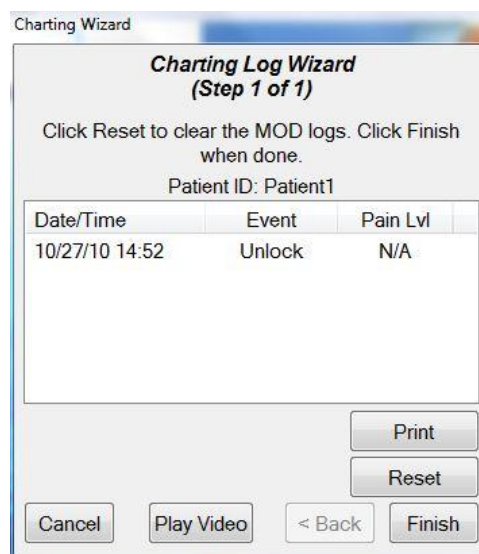


Figure 23: Charting Log on MOD[®] display screen

- Click or touch print to print the charting log that appears on the screen. The computer must be connected to a printer to perform this task.
- Click or touch **RESET** to clear the charting log on the screen. Confirm the reset action (Figure 24).



Figure 24: Charting Log reset option window

- If you select **YES** to reset the charting log on the screen, the patient's data will be transferred into the computing device connected to MOD[®]. **NOTE: USING DIFFERENT COMPUTING DEVICES (MULTIPLE COMPUTERS) TO OBTAIN CHARTING INFORMATION WILL RESULT IN FRAGMENTED RECORDS.**
- Select Finish to return to the main menu icons (Figure 25).

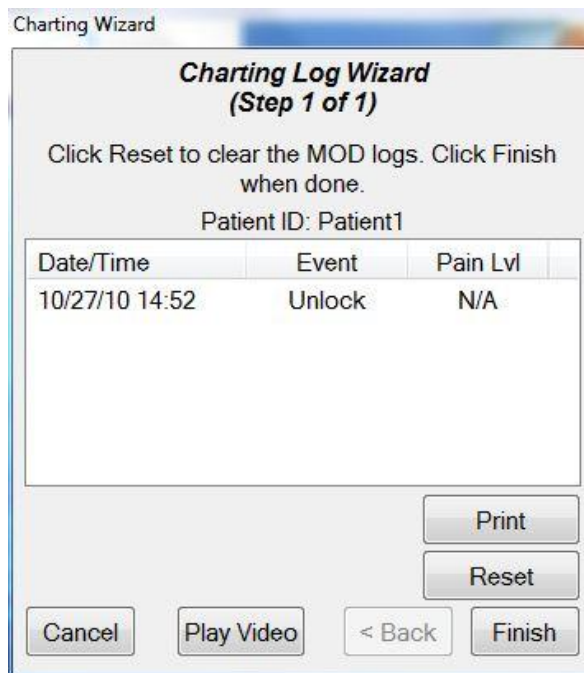


Figure 25: Charting Log Wizard Complete screen

Discharging a Patient from the MOD[®]

Once the patient has completed the use of their MOD[®], it is necessary to:

- Discharge the patient from the MOD[®] device.

- Access and save the patient's medication use records that are stored in MOD[®] memory (the Charting Log) to transfer into the medical record.
- Clear the patient's dispense order programming from the MOD[®] memory so that the MOD[®] is ready for a new patient's program.
- Dispose of any remaining medication in the MOD[®] Medication Tray Insert according to the facility's policies and procedures.

You will need a preprogrammed MOD[®] Nurse Card to complete the Discharge Module.

1. Connect the device to your computer using the USB cable.
2. Select the MOD[®] programming wizard from your Windows Start list or Desktop..
3. Select the **Discharge** icon.

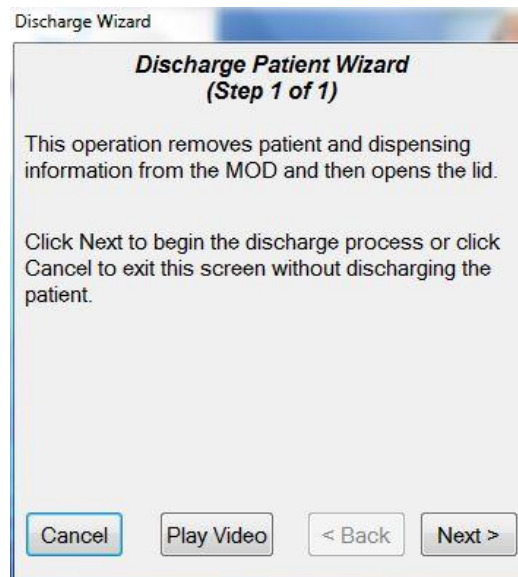


Figure 26: Discharge Patient Wizard

4. Select **NEXT** to proceed with Discharge. When **NEXT** is selected, the dispensing information is removed and downloaded into the semi permanent database. Clicking **NEXT** also opens the MOD[®] cover for tray removal. The window states that the discharge patient process is complete.

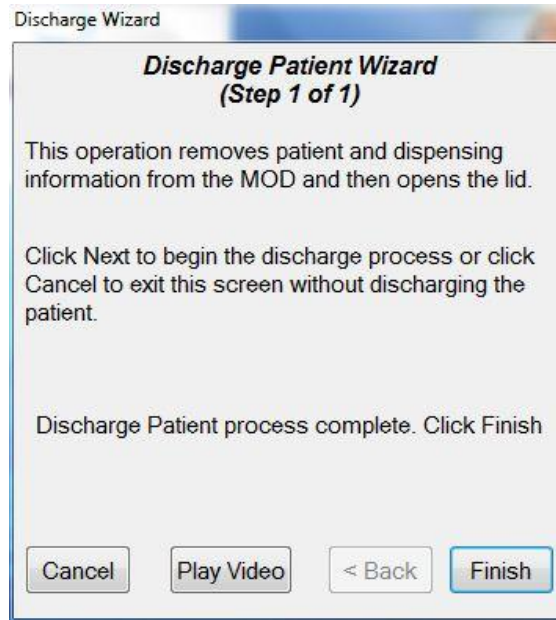


Figure 27: Discharge Patient Confirmation window

5. After removing the medication tray, select FINISH and close the top of the device (Figure 27). If you fail to open the MOD[®] cover after selecting NEXT and FINISH (completing the Discharge) the cover can be opened by pressing zero without the need of the MOD[®] Nurse Card.

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, contact Avancen Customer Service to return the device. Avancen recommends that the MOD[®] device be checked by your facility's Biomedical Department or qualified service personnel at least once every 12 months or as indicated by hospital 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.

Regular Maintenance between Patients

Check	Action
Exterior	<ul style="list-style-type: none">• Clean as recommended in next section.• Check for damage (i.e., cracks, dents, deformities).• Confirm that the MOD[®] cover is well aligned, closes without interference, and locks securely.• Verify that the MOD[®] IV Pole Security Holder is secure, locking, and functioning properly.
Labels	<ul style="list-style-type: none">• Check for readability or missing labels.
Pain Scale Touchpad and RFID Reader	<ul style="list-style-type: none">• Confirm that the front panel touchpad is securely attached to case and that no corners are peeling.• Check the RFID Reader area for damage.
Charging Unit (A/C Adapter)	<ul style="list-style-type: none">• Inspect the A/C adapter (cord and charging unit) for damage, cuts, or deformities. If damaged, replace the entire unit.
Battery	<ul style="list-style-type: none">• Recharge the MOD[®] with A/C adapter unit (for at least 5 hours).• Check BATTERY indicator status light.• Make sure BATTERY charge indicator lights orange during recharge. The light will extinguish when the device is fully charged.
Power Check	<ul style="list-style-type: none">• Plug in the device to make sure it runs correctly.

Cleaning

- The Avancen MOD[®] is designed to be resistant to fluid spillage from any direction, but it is not to be immersed in solutions. Keep the surface clean, dry, and free of fluid spillage at all times. Do not use MOD[®] in the shower, sauna, or steam bath and do not position MOD[®] where it could accidentally be dropped into a container of fluid (e.g. basin, tub, or toilet.)
- To prevent electrical hazards, unplug MOD[®] and its A/C adapter before cleaning.
- Only MOD[®] external parts should be cleaned/disinfected, including the medication tray dispense wheel. Clean MOD[®] 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, disinfect, or sterilize any part of the MOD[®] device by autoclaving. This may damage the device and will void the warranty. Disinfect MOD[®] external parts only, using approved cleansers or disinfectants (hand wipe only).
- MOD[®] is classified as a non-critical item since it comes in contact with intact skin. If MOD[®] 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[®], security holder, and IV pole clamp with a soft, slightly damp cloth, using one of these low-level hospital disinfectants. Follow the commercial product directions for dilution and proper usage:

Approved Cleansers
Ethyl or isopropyl alcohol (70-90% concentration)
Quaternary ammonium compounds
A solution of 10% bleach 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.
- 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 zero on the pain scale. A MOD[®] nurse card is not necessary to open an unprogrammed MOD[®].
- 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 NOT RECOMMENDED FOR ROUTINE CLEANING OF THE MOD[®]:

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.

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 policy and procedures of your institution. Do not dispose of the device without first contacting Avancen Customer Service.

Appendix

Radio Frequency Identification technology is part of the MOD[®] wireless system for identification and validation of the correct patient and nurse operator of the device. MOD[®] 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.

Passive RFID tags are present in the patient wristband and Nurse Card. They 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. THERE ARE NO OTHER WARRANTIES.
- 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 warranty is not transferable and applies only to the original purchaser or leaseholder of the Product.
- Avancen MOD Corporation, as its sole obligation under this warranty, will replace or repair at its option any Product that does not conform to this warranty. Products may be repaired or replaced with new or with refurbished items. This limited warranty does not cover defect in appearance, cosmetic, 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 purchase the Product in the United States of America.
- The warranty is void and Avancen MOD Corporation will not be responsible for damage resulting from any (i) deviation of use from operating instructions as printed in the Avancen MOD Corporation User Guide 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; (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.

Sample Patient MOD[®] Use Checklist

MOD[®] PATIENT USE CHECKLIST

Patient Education

- _____ The patient has received instruction in MOD[®] 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
- _____ The patient was given the Patient Guide on MOD[®] 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.
- _____ The patient agrees to call the nurse for any device malfunction.
- _____ The patient agrees to call the nurse if the red battery light comes on.
- _____ The patient understands that the orange battery light indicates that the battery is charging (no action required on their part).
- _____ 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.
- _____ 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[®] 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 charged. To verify that the MOD[®] is ON, attach the MOD[®] to its A/C adapter and plug the unit into an A/C outlet. Refer to the troubleshooting table below for common issues and corrective actions.

ISSUE	CORRECTIVE ACTION
MOD[®] does not turn on or activate	<p>Attach the MOD[®] to its A/C adapter and plug the unit into an A/C outlet.</p> <p>If the device has never been programmed or is not programmed begin with linking it to your computer (programming device) with the supplied USB cable to initiate the new patient program.</p> <p>If the device has already been programmed, try activating the unit again with the Nurse Card or patient wristband programmed into the device.</p>
MOD[®] does not respond to RFID activator (card or wristband)	<p>Verify that you are using the correct RFID card/wristband programmed for the MOD[®] device in question.</p> <p>Verify that the MOD[®] has been programmed and that it is in “dispense mode.” To determine if MOD[®] has been programmed, touch the Avancen logo for 3-5 seconds and wait. If the blinking light blinks slowly and continuously, then the MOD[®] has been programmed.</p>
Green READY light does not illuminate when the dispense time interval is reached	<p>Connect the device to your computer and use the Modify/Reload pathway to check the current program within the device for the correct lockout interval.</p>
MOD[®] cover will not lock when it is closed	<p>Repeat the process by pushing down the cover into the lock a second time.</p>
“Low Battery” light does not turn orange when attempting to charge the MOD[®]	<p>Verify that the MOD[®] is plugged into a working A/C outlet (120V, 60 Hz). If the MOD[®] has been previously charged, its battery may be fully charged and will not accept additional charge.</p> <p>If possible, to verify that the A/C adapter is not broken, use an A/C adapter from another MOD[®].</p>
MOD[®] cover will not open when the Nurse Card is used to open the device	<p>Repeat the maneuver and place your finger under the cover to assist the cover to fully open when the dispenser wheel turns.</p>
Dispenser wheel will not turn	<p>The disposable tray may not be seated properly, causing the wheel to “jam.” Use the Nurse Card to unlock the cover and check the disposable medication tray to be sure it is not interfering with the turning of the dispenser wheel. Close the cover and repeat the command.</p>
MOD[®] Nurse Card lost or destroyed	<p>Each facility will receive a MOD[®] master card that can be used to access the MOD[®] programs within a device. The master card must be stored in a secure area of the facility available only to administration personnel. Use the master card to access and reprogram the device with another card; then return the master card to its secure area.</p>

Disclaimer

All recommendations, information, and descriptive literature supplied by Avancen MOD Corporation or its agents are believed to be accurate and reliable, but do not constitute warranties. The information in this document has been carefully examined and is believed to be entirely reliable. 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.

Trademarks

MOD[®] is a registered trademark of Avancen MOD Corporation. All other trademarks are the property of their respective owners.

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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