

MARKEN TRAINING GUIDE

- Driver's must be "study trained" for these jobs
 - Driver's name and cellphone number must be provided for alerts
- **ONLY PATIENT** or **REPRESENTATIVE** can collect the drug. (Names are on the booking form)
 - **If someone else is present**, must have their ID information and call the AEMARKEN team at **775-372-9019**
- Drive must have **2 copies** of the MARKEN HAWB forms
 - Collection site signs under SHIPPERS SIGNATURE **BOX 1**
 - No photo ID Type required UNLESS tendering. (in BOX 1)
 - Driver signs in Collected in good order & condition **BOX 2**
 - Receiver does not sign in Received in good order & condition **BOX 3**

Special Instructions	Collected in good order & condition	Received in good order & condition
Pls preconditioned USB TT4/Credo Series4 2+8c Always call Marken upon collection & upon delivery to provide verbal temp. readings display on TT4. If any excursion/bell call ASAP. Recover/credo/TT4	Signature Driver Completes This Section	Signature BLINDED INFO - DO NOT WRITE Receiver Does NOT Sign
Shippers signature Pickup Site Rep Completes this Section	Printed name	Printed name BLINDED INFO - DO NOT WRITE
Printed Name	Date Time	Date Time
Date Photo ID Type	<small>NOTE: The goods described above are accepted in apparent good order and condition (except where noted by shipper or noted above) for delivery to the stated consignee, subject to Marken's Standard Terms and Conditions, available for review at http://www.marken.com/terms-and-conditions.aspx, which limit Marken's liability</small>	

- **No signatures: Driver prints names, enters date, and time 24:00 form.**



AIRWAYBILL



Marken Philadelphia
215 W. Bridgewater Road, Bridgewater Business Park, Aston, PA 19014, United States

636X14513139

Shipper Blinded Data Blinded Data Blinded Data Blinded Data Blinded Data		Consigned Norton Healthcare Study Clinic 315 E. Broadway Suite 195 Lexington, KY 40202		Waybill Number 636X14513139
Contact Blinded Data		Contact Marti Gardner		Schd Collection 16 Nov 2020
Patient Id US10100-004336		Reference ENSEMBLE OPP:ceabtrial_T43-US10100		Schd Delivery 16 Nov 2020
Telephone Blinded Data		Telephone 502.629.3550		Client Account US1485

Content Description	Pcs	Range (°C)	Kgs	Origin			Destination			
				Type	Region	Destination	Type	Region	Destination	
Biological Sample - Human CAT B	1	+2 to +8	3.00	HANOVER	2-30-008	Summit	MARKEN	21	21	10
TOTALS	Pieces	Actual Kgs	3.00	Volu Kgs	2.38	Value	0.00			

Special Instructions Driver must meet Participant at agreed time if Strictly follow NO TOUCH POLICY MARKEN to provide 2-8 degree packaging SAME DAY DELIVERY TO SITE		Collected in good order & condition	Received in good order & condition
Shippers signature Blinded Info - DO NOT WRITE		Signature DRIVER SIGNATURE ONLY	Signature
Printed Name Blinded Info - DO NOT WRITE		Printed name DRIVER ONLY	Printed name
Date	Photo ID Type	Date	Time

NOTE: The goods described above are accepted in good order and condition for delivery to the stated consignee, subject to Marken's Standard Terms and Conditions, which form part of this airwaybill, which form Marken's liability.



636X14513139

Marti Gardner
Norton Healthcare Study Clinic
315 E. Broadway
Suite 195
Lexington, KY 40202

Package
1 of 1

Tel: 502.629.3550

MARKEN DTP/DTF Booking Form

- Used when picking up from or delivery to PATIENT HOME only
- Check DTP/DTF-AWB
- Subject ID (MANDATORY)
- Ask patients if they want to enable VISEO (tracks shipment in real time)
 - If yes, collect patient's email address or phone number
- Driver must:
 - read temperature of drug samples
 - note the device serial number
 - and remind the receiver that the drug must NOT be used if temperature excursion (*drug must be in specific temp range*)
- Ensure completed document is returned to dispatch within 48 hrs. and original documents are destroyed, only when verified copy is with MARKEN.

Driver's **MUST** adhere to the following:

- Wear company uniform and photo ID at ALL-TIMES.
- Review the delivery email for any special instructions, requirements, temperature/ alarm temperature readings.
- Behave professionally and respectfully.
- DO NOT ENTER PATIENT'S HOUSE, even if asked to by patient.
- Request to see government issued ID of patient or representative and confirm their identity, same as email.
 - Driver's Name
 - Time/ Date Identity has been confirmed
- Avoid direct contact with the product/ contents that are being delivered. Handover shipping box to the patient and wait for return shipment to be packed by the patient.
- If the patient or representative (as named in the email) is not available, **please CALL MARKEN!** DO NOT DELIVER PACKAGE TO ANYONE ELSE.
- Handover the package to the patient and asking them to kindly unpack the product.

- DO NOT DISCUSS the trial, medical condition, or experience with the medication at the home with the patient, patient's representative, or anyone else.
 - If the patient tries to discuss anything related to these topics, please politely respond that you are not allowed to discuss such topics. And if they have questions or concerns to contact their doctor.
- Any questions or concerns to call Marken's Depot at 631-396-7545.
- All patient information must be protected from access by unauthorized persons.

DTP: Delivery to Patient Instruction Checklist

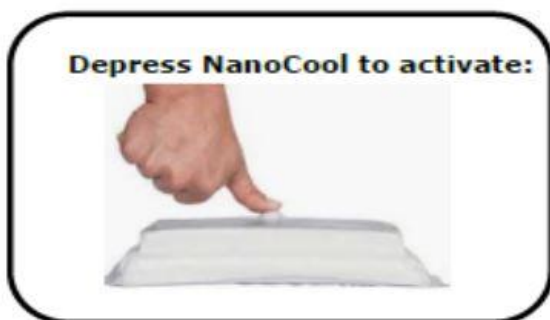
- Collection from the site
 - Driver to check temp and ensure logger is running and temp is within range
 - Site rep to pack the contents inside the container
 - Site rep to assign the AWB as shipper
 - Sign/ Date HAWB
 - Close and seal the shipment container with tape
- Delivery to the patient
 - Request to see a government issued photo ID for recipient name on Rapid Response Booking form and confirm their identity.
 - Retrieve temp monitor and check for alarms
 - No alarm- continue
 - Alarm- see further instructions
 - Note on the booking form: Patient name ID was verbally verified, and shipment delivered on date and sign and date.
- Post Delivery
 - Ensure that the completed shipment documentation is returned to your dispatch office within 48 hrs. and stored any original DTP documentation in a secure location.

DFP: Delivery from Patient Reminders

- State you represent Marken and are picking up/ delivering a shipment
- Do NOT cross the threshold of a patient's home under any circumstances
- Avoid direct contact with the contents being shipped
- Do not discuss the patients/ representative anything related to the medication, study, or patient's medical condition, but redirect them to MARKEN or their respective doctor.
- All patient information must be protected from access by unauthorized persons.

DFP: Delivery from Patient Instruction Checklist

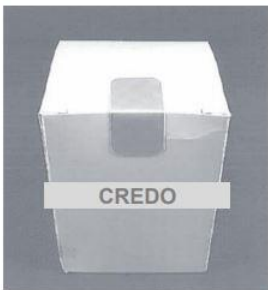
- Collection from the patient
 - Arrive with a NanoCool box and depress the button to activate the cooling (*once active the word NANCOOL will become dark blue*)
 - Open the NanoCool and remove the cooling engine
 - Allow patient to place contents inside the NanoCool box
 - Replace the cool engine
 - Close and seal the shipping container with tape
 - Driver only sign the Marken AWBs as collected in Collected in good order & condition BOX 2



- Delivery to the site
 - Handover the box
 - Driver only sign the Marken AWBs as delivered in Collected in good order & condition **BOX 2**
 - Record Pickup On Board (POB) milestone in xMaestro
 - Return completed AWB and completed Driver Instruction Checklist to Marken Office within 24 hrs. of delivery.

Collection- Prior to Packing/ Paperwork

- Driver ONLY handles the box and TT4; The Site ONLY handles the IMP (medication)



- Credo box is preconditioned to **2-8°C or 15-25°C**
- Credo must be **packed quickly** to avoid temperature excursions during packing process
- TT4 must always remain in the Credo box
- Receive supporting material from the site and put in the second box (outer box) so that the Credo box does not move inside.

1 Supporting Material inside the outer box

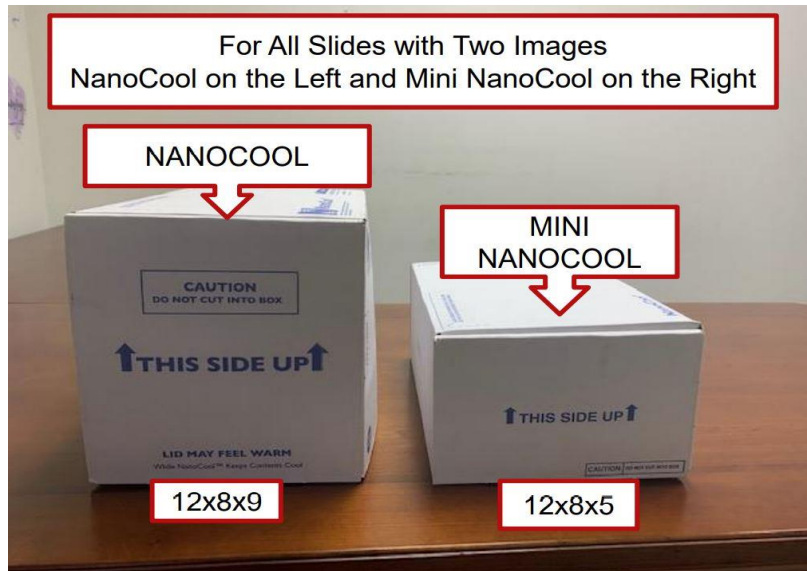
MARKEN CREDO RE-USABLE PACKAGING (3rd box involved)



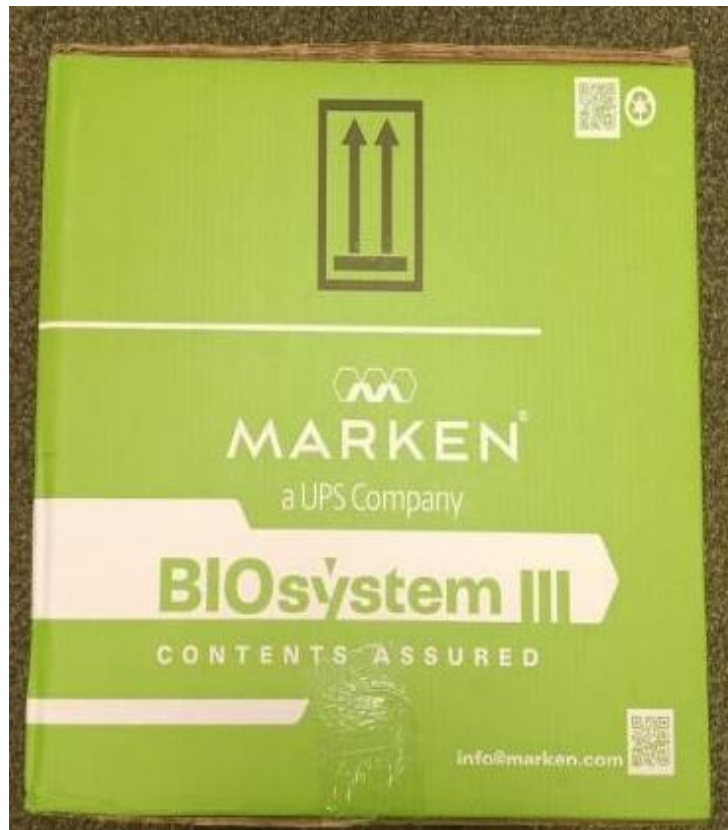
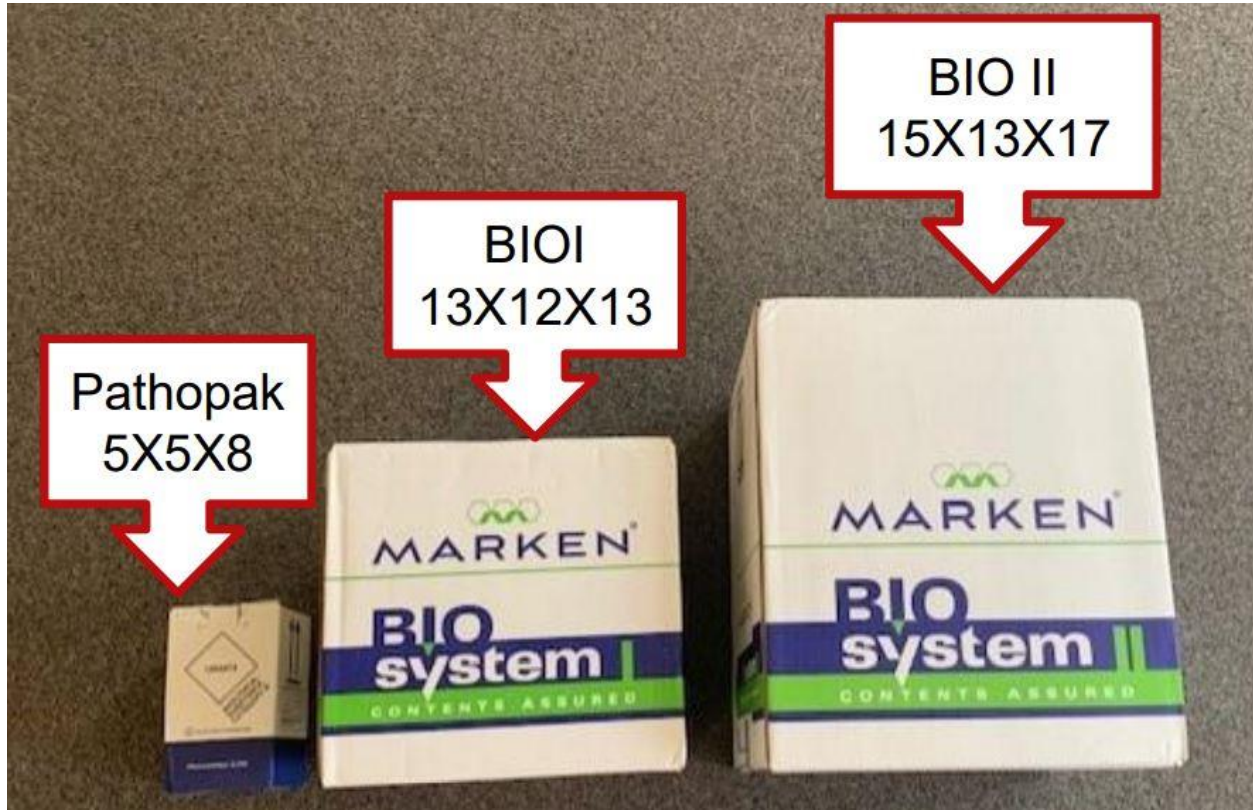
MARKEN CREDO RE-USABLE SMART BOX



NanoCool and Mini NanoCool Boxes

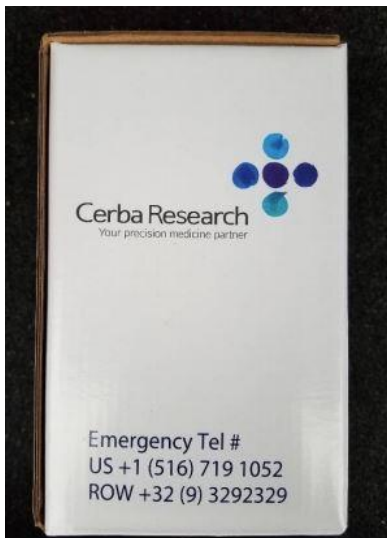


MARKEN BOX EXAMPLES (Outer Box)



MARKEN BOX for CERBA (Pathopak 5x5x8 as shown in previous page)

- Place the MARKEN HAWB on one side labeled UN3373
 - Note: There are two sides labeled UN3373, place on any one side



TT4 Temptale Ultra Temperature Monitor

Instructions at Pick up site:

- 1) Record the Temperature
- 2) Check the ALARM
 - a. If you see a flashing **X** you must call the MARKEN Team or your site dispatch
- 3) Press green **START** button down for 4 seconds, this sets the date/ time stamp for when the medication has been **placed** into the CREDO/CoolGuard.



TT4 running,
alarmed.



TT4 serial number/bar
code.

Instructions at Delivery (patient home):

- 4) Record the Temperature
- 5) Check the ALARM
 - a. If you see a flashing **X** you must call the MARKEN Team or your site dispatch
- 6) Press red **STOP** button down for 5 seconds, this sets the date/ time stamp for when the medication has been **removed** into the CREDO/CoolGuard.
 - a. And shuts the TT4 device down.



TT4 stopped, no alarm.

SUMMARY

• Delivery to Patient Home

- The driver or dispatch at any time can **NOT** call the Pickup site or the patient. All correspondence must go through MARKEN ONLY.
- When uniformed driver arrives patient home, he/ she must state they are representing MARKEN and present photo ID indicating his/ her name and company
- The driver can **NEVER** cross threshold and enter the patient's home under any circumstances.
- The driver **MUST** request government issued ID of the patient or representative and confirm name matches the booking form.
 - Then they must document that the identity was verified on the booking form and/ or driver's checklist.
- If no patient or representative mentioned on booking form is not home, **the shipment will not be delivered.**
 - CONTACT MARKEN for further instructions.

- Confidentiality

- Drivers are **NOT** allowed to discuss with the patient or any individuals about the medication, study trial, disease, or treatment.
- All involved will ensure that patient data is **NOT** shown on client documents such reports, waybills, and invoices.
 - Build corresponding jobs and report POD by PATIENT ID # ONLY
- Do **NOT** take a picture of the patient's or representatives ID cards
- Do **NOT** store or record any work-related data on your personal devices or personal accounts.