

Receipt & Return handling instructions

Attention! Please read the enclosed instructions or scan the QR code to view the explanatory video!

Achtung! Bitte lesen Sie die beiliegende Anleitung oder scannen Sie den QR Code um das Erklärvideo anzusehen!

Attention ! Veuillez lire les instructions ci-jointes ou scanner le code QR pour visionner la vidéo explicative !

Attenzione! Per cortesia leggete le istruzioni sotto riportate o scansionate il codice QR per accedere a un video di spiegazione.

¡Atención! Por favor, lea las instrucciones adjuntas o escanee el código QR para ver el vídeo explicativo.



Scan me



Please contact in case of questions on:

Shipper and returns of shipper:

Tel +49 69 69 76 790, support@envirotainer.com

Data logger:

support@controlant.com (currently no phone support)

Any other topics with the shipment:

Your CRA/monitor or Roche/Genentech Representative contact

Envirotainer°

envirotainer.com
+49 69 69 76 790
support@envirotainer.com

Receipt instructions

Step 1 Open the outer cardboard > Open the lid of the shipper > Remove the upper cold pack.



Step 2 Remove the inner carton with products and data logger.



Step 3 Take the data logger out of the inner carton. **Document the time and date of shipment receipt on the Delivery Note/Consignment Request. Transfer the IPs to the pharmacy-controlled temp unit matching the label requirements of the product.**



Press & hold stop button for 5 to 20 seconds!

❏ Press and hold the stop button **for at least 5 and not longer than 20 seconds** until the blue indicator lights up briefly and the top line of display status changes from **Shipping** to **Stopping** and then **Stopped**.

✕ If the cloud icon is crossed out, the logger has no connection to upload the temperature recording and the stopping date and time of the logger. Wait a couple of minutes, move the logger near a window and check on the logger status to see if it shows **Stopped** status and a cloud icon has a check mark. If the issue persists, contact the support at support@controlant.com.

🚨 If the red alarm light is blinking every 5 seconds, a temperature excursion has occurred. After stopping the device, **quarantine the IP (investigational product)* physically in your site storage unit as per product label conditions and in IRT (IxRS)**. Contact your CRA/Monitor or Roche/Genentech Representative providing them with the shipping documentation including the shipment temperature report and wait for further guidance.

For temperature report download, scan the QR code on the page 2 of the delivery note or go to <https://roche-clinical.share.controlant.com>

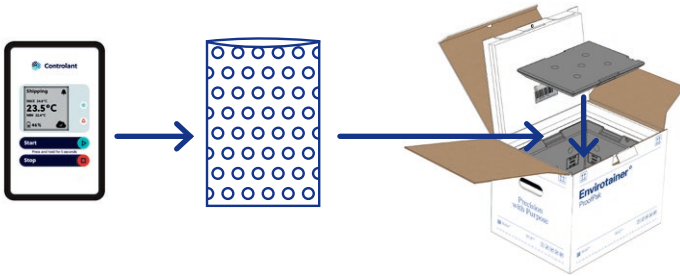
Archive the temperature report and shipping documents in your investigator site file (ISF) [or Pharmacy Site File (PSF) if used].

If upon downloading the temperature record there are no temperature excursions noted and the quality of the IP is listed as "Released" on the downloaded temperature report, record the shipment in IRT (IxRS) (as applicable) and transfer it to your local temperature controlled unit as per IP label conditions.

*Investigational Product (IP) - for the purpose of this form includes drug, biologic, device, drug/medical device combination or diagnostic product under investigation.

Return instructions for logger and shipper

- Step 4** After stopping the logger, place the logger inside the protective pouch, remove tape and seal, and place the pouch back into the shipper. Place all cold packs into the shipper.



Please do not return any IP with any returning shipper. Please consult with your CRA/Roche/Genentech representative on returning IP.

- Step 5** Remove or cover any Dangerous Goods labels, if present on the box.

- Step 6** Close the lid of the shipper > Fold flaps in following order: Fold in flap **A** > Fold in flap **B** > Fold in flap **C** > Use adhesive tape on the back of flap **C** to seal the lid > Make sure that return label is on flap **C** > Hand over box to **DHL**



- Step 7** Check that return label is visible on flap **C** on the outside of the shipper and shows Envirotainer Würzburg as return address.

- Step 8** Hand-over shipper to DHL Express as previously scheduled on DHL Express portal "EPP". Please refer to the site user guide for country specific return processes.

- Step 9** **If the logger has not been stopped timely:**

Scenario 1: A logger has not been stopped when the shipment was received and recorded a "false temp deviation" as it was left on the table while the IP was timely placed in the required temperature conditions.

Required actions:

- Contact your CRA/Roche/Genentech representative immediately and explain the time inconsistency between the time and date of logger stop and the time and date the IP was transferred to the pharmacy-controlled temp unit.
- Attach the completed delivery note showing the date and time was transferred to the pharmacy-controlled temp unit.
- Quarantine in IRT (IxRS) and physically at your site the IP.
- Do not use the IP until a confirmation is received from your CRA/Roche/Genentech representative contact that is suitable for use.
- File this correspondence in your pharmacy site file or ISF


Scenario 2: A logger has not been stopped and sent back with the shipper box.

Required actions:

- Notify immediately your CRA or your Roche/Genentech representative contact and explain the situation.
- Attach the completed delivery note showing the date and time the IP was transferred to the pharmacy-controlled temp unit.
- Quarantine in IRT (IxRS) and physically at your site the IP.
- Do not use IP until a confirmation is received from your CRA or your Roche/Genentech representative contact that the IP is suitable for use.
- File this correspondence in your pharmacy site file or ISF.

Frequently asked questions (FAQ)

FAQ on data loggers

Question	Answer
Is this a disposable logger?	No, this is a multi-use logger and must be returned together with the shipper. Refer to the instructions above.
Who can I contact if I have any questions on the data logger?	Please contact data logger provider Controlant at support@controlant.com currently no phone support available.
How can I download the temperature report?	There are two options to download the temperature report: 1. Scan the QR code on the delivery note/consignment request. This will open the report directly or 2. Go to https://roche-clinical.share.controlant.com and enter site ID and consignment number, both found on the delivery note. Follow instructions on the web page.
No temperature report available for your shipment on the Controlant cloud. What do I need to do?	Your data logger did not stop properly. Please review Step 3 and check the logger screen (also please refer to the question below). If the issue persists, contact the logger provider at support@controlant.com.
How can I stop the data logger in case of a weak or non-existing GSM signal? This icon is displayed  .	Wait a couple of minutes or move the logger near a window and try again to stop the data logger. If the issue persists, contact the logger provider at support@controlant.com .
How can I return the data logger after DHL already collected the empty shipper?	Please return the left behind data logger in the next returning shipper for your clinical site. In case of questions on the return send them to your CRA/Roche/Genentech representative or send an email to support@controlant.com .

FAQ on shippers

Question	Answer
Who to contact if I have any questions about the shipper or the return process?	Please contact Envirotainer directly for any further support on shippers: Tel. +49 69 69 76 790 or email to support@envirotainer.com
Is this a disposable shipper?	No. It is a multi-use shipper box, which needs to be returned back to the service partner Envirotaine for refurbishment.
When will the empty shipper be picked-up?	The pick-up will be on the next working day after delivery
Who organizes pick-up and shipping documents?	Pick-up will be initiated automatically by Envirotainer. Each shipper is already pre labeled with return shipping documents. Please follow the return instructions on the inside flap of the outer carton.
Which components belong to the shipper?	There are 6 cold packs which must be all placed back and returned with the shipper.
Can I return products or other materials in a returning shipper?	No. The shipper does not return to the shipping depot. It goes directly to the service partner Envirotainer for refurbishment. Do not return the IP with the shippers.
How can I order the pick-up of the returning shipper box on the day of delivery?	After unloading of the shipper box, please send an email to support@envirotainer.com with the following email header: "Same day pick-up of returning shipper box" and include the following information: <ul style="list-style-type: none">• Full address of the clinical site• Name, phone and email address of contact person• Attach picture of the shipment label on the flap of the box• AWB number If pick-up is ordered at Envirotainer prior 12:00 CET the chance for same day pick-up is around 80%. Otherwise, it will be the day after as the default pick-up.
How can I change the pick-up location of the returning shipper box?	After unloading of the shipper box, please send an email to support@envirotainer.com with the following email header: "Changed pick-up location for returning shipper box" and include the following information: <ul style="list-style-type: none">• Full address of the clinical site• Name, phone and email address of contact person• Attach picture of the shipment label on the flap of the box• AWB number The changed pick-up location must be requested prior 16:00 CET as otherwise the delivery location will be used as default pick-up location.