Controlant Onsite Temperature Monitoring Playbook for Sites

Version 3.7

Controlant

Contents

Receiving the Box

- What to do after receiving your box
- What to do if there was an excursion during shipment

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THE "STOP SHIPMENT" BUTTON <u>DOES NOT</u> DEACTIVATE MONITORING!

The logger is always on!

Onsite monitoring can only be deactivated by your site's point of contact through the onsite monitoring link in the monitoring alert emails

Receive Logger

Press the Stop Shipment button for 5 seconds to end the shipment to your site and begin onsite monitoring

1 — 5 seconds

2 — OK to use product

3, 4, 5 — Check shipment quality report for product status

Reading the Logger

Shipment Status:

- **Green** – There were no excursions on the way and quality of the shipment is **Good.** Await the quality report for confirmation.
- **Red** - Temperature deviation during shipment occurred, quality **Undecided** or **Bad.** Await the quality report for guidance.
- You can find quality status in the quality report email sent after shipment. Pfizer may change quality from *Undecided* to **Good** or **Bad**. If so, a new report will be emailed to your site point of contact.

Connection:

- **Green** - Sufficient cellular connection, logger is connecting to the cloud.
- **Red** - Insufficient cellular connection, logger is not connecting to the cloud.

Battery:

- **Green** - Battery above 4V ~ 90%
- **Red** - Battery below 4V ~ 90%
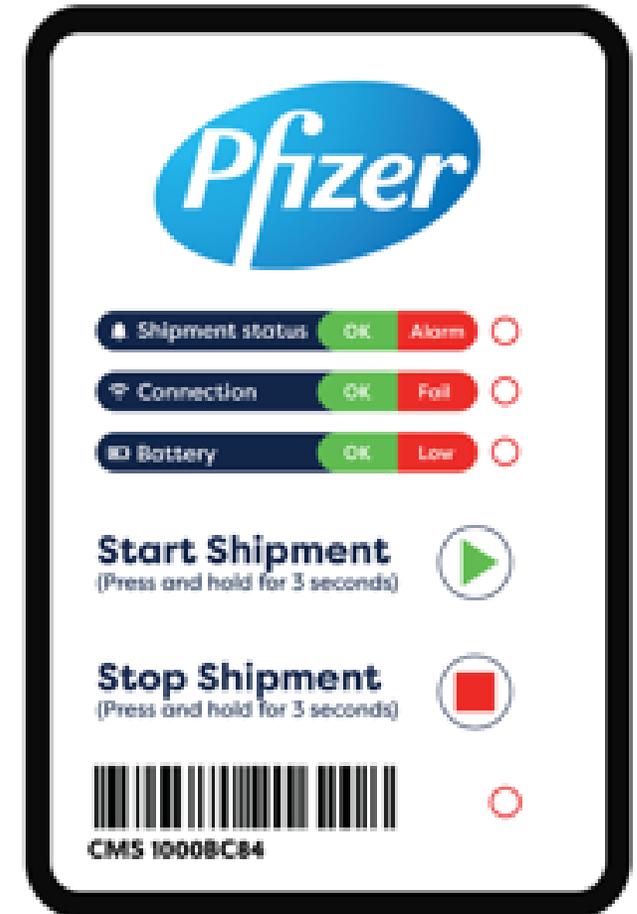
Shipment Quality Reports

- You will receive a quality report from reports@controlant.com after your shipment is delivered

- Reports have 1 of the following statuses:
  - Good – Shipment is OK for use.
  - Undecided – Shipment requires further examination by Pfizer. Do not use or unpack until you receive an updated quality report. Undecided reviews may require multiple hours. **Wait for a decision.**
  - Bad – Do not use this shipment.

THE RETURN SHIPPING LABEL IS INCLUDED IN THE BOX. DO NOT THROW IT AWAY!

Keep return shipping label!

Onsite Monitoring

- Daily alert emails
- How to turn off monitoring for an empty box
- How to opt out of all onsite monitoring for all boxes
- How to add contacts
- How to change your primary point of contact

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DO NOT USE INTERNET EXPLORER!

Use Chrome, Firefox, Edge, or Safari
Contact your local IT team immediately if you do not have one of these browsers installed and enabled

Daily Onsite Monitoring Email

Once onsite temperature monitoring starts, an email will be sent to site contact(s) daily.

1 Click the link to the onsite monitoring form from your email.

2 Select the <u>Opt out of monitoring, I have freezer</u> button to opt out of onsite monitoring if you will store the products in your own vaccine freezer and not in the box(es).

3 You can enable or disable your <u>Primary contacts</u>. Your Primary contact cannot be deleted but may opt out of receiving alerts/phone calls if a temperature deviation occurs. At least one contact must be enabled.

4 Add/enable/or disable <u>Other contacts</u> that will receive alerts and phone calls in the case of a temperature deviation. You may add up to eight (8) additional contacts.

5 If you are only editing contact information, select <u>update contacts</u> at the bottom of the form.

6 If you need assistance or would like to include a message, select <u>Other</u> at the bottom of the page and type in a message.

7 Select <u>Submit</u>.

Deactivate Monitoring for 1 Box: 1/2

Turn off monitoring once you are no longer using it to store vaccine

Subject Line: Onsite monitoring for your vaccines -
order #OS – 80########)
From: onsitemonitoring@controlant.com

2. Click on the active logger box
(some orders have multiple boxes)

1. Open link to view onsite monitoring

Onsite monitoring

1 box is being monitored.

Click here to view temperature status,

assign more contacts or stop monitoring

If any of your products in the box(es) referenced below are not released, please make sure to match the boxIDs with the information below and keep the products separate. A follow up email will be sent within 48 hours containing further instructions.

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Onsite monitoring status

You can stop the monitoring of loggers by clicking the boxes below and then saving at the bottom of the page.

Active

Logger ID: ▮Redacted▮
Box ID: USU▮Redacted▮

Active

Deactivate Monitoring for 1 Box: 2/2

Turn off monitoring once you are no longer using it to store vaccine

3. Box will turn red and display warning

4. Save to stop monitoring alerts

Opt Out of All Onsite Monitoring

Opting out will disable all onsite monitoring alerts for current and future shipments

Subject Line: Onsite monitoring for your vaccines - order #OS – 80########)

From: onsitemonitoring@controlant.com

1. Open link to view onsite monitoring

Onsite monitoring

1 box is being monitored.

Click here to view temperature status, assign more contacts or stop monitoring

If any of your products in the box(es) referenced below are not released, please make sure to match the boxIDs with the information below and keep the products separate. A follow up email will be sent within 48 hours containing further instructions.

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2. Scroll to bottom of page

Remember to click save before you exit.

Update contacts

Other

Opt out of monitoring, I have freezer

You are about to:

☑ Opt out of future onsite monitoring. When the next shipment arrives onsite monitoring will not start automatically, but you will have the option to click a link to opt in again

Cancel   Save

3. Select opt out of monitoring, I have freezer

4. Click Save

Add Contacts to Onsite Monitoring – 1/2

Add contacts to receive monitoring emails, texts, and phone calls

Subject Line: Onsite monitoring for your vaccines - order #OS – 80########)
From: onsitemonitoring@controlant.com

1. Open link to view onsite monitoring

2. Scroll down and select "Add New Contact"

Add Contacts to Onsite Monitoring – 2/2

Add contacts to receive monitoring emails, texts, and phone calls

3. Update contact information
(Use 24/7 phone #)

4. Click "Save"

Remove Contacts from Monitoring – 1/2

Remove contacts from onsite monitoring emails, texts, and phone calls

Subject Line: Onsite monitoring for your vaccines - order #OS – 80########)
From: onsitemonitoring@controlant.com

Onsite monitoring

1 box is being monitored.

Click here to view temperature status,

assign more contacts or stop monitoring

If any of your products in the box(es) referenced below are not released, please make sure to match the boxIDs with the information below and keep the products separate. A follow up email will be sent within 48 hours containing further instructions.

1. Open link to view onsite monitoring

Contact enabled

Contact name

Alex

Email

alex@email.com

Mobile

5269978

| Delete contact | Disable |

+ Add new contact

2. Scroll down page and select "Add New Contact"

Remove Contacts from Monitoring – 2/2

Remove contacts from onsite monitoring emails, texts, and phone calls

Contact enabled

Contact name

Testy Testerson

Email

test@test.com

Mobile

123456789

Delete contact | Disable

Update contacts

Other

Opt out of monitoring, I have freezer

You are about to:

☑ Update contacts

Cancel | Save

3. Select "Disable" to turn off alerts or "Delete" to completely remove the contact

4. Click "Save"

Change Primary Point of Contact

Your site POC was assigned by your state/jurisdiction immunization agency. **Only you can add or change contact information**. If you believe you have been assigned as a point of contact in error, please do the following:

1. Notify your organization and identify the correct point of contact for current shipments and onsite monitoring
2. Notify you State Vaccine Immunization Program Manager of the correct point of contact for future shipments. The list of Program Managers is here: https://www.immunizationmanagers.org/page/MemPage
    *   **If you do not notify your State Vaccine Immunization Program Manager, your contact information will not change.**

Reactivate Onsite Monitoring

- Email onsitemonitoring@controlant.com to reactivate monitoring

- Include:
  - Subject line: Opt in Logger ID: CMS########
    - The Logger ID# is on the logger and starts with CMS
  - Body: State you would like to opt into onsite monitoring
    - "We would like to opt into onsite monitoring."

Returning the Box

- How to return an empty box
- How to get a new return shipping label

Controlant

How to Return the Box – 1/2

Subject Line: Onsite monitoring for your vaccines - order #OS – 80########)
From: onsitemonitoring@controlant.com

1. Open monitoring email and scroll down

Onsite monitoring

1 box is being monitored.

Click here to view temperature status,

assign more contacts or stop monitoring

If any of your products in the box(es) referenced below are not released, please make sure to match the boxIDs with the information below and keep the products separate. A follow up email will be sent within 48 hours containing further instructions.

Are the box and data logger ready for collection?

Please confirm whether the box and the data logger inside are ready to be collected, or if you plan to continue to use the box.

Please confirm collection or usage

2. Scroll down and select "Please confirm collection or usage"

Current as of February 2, 2021, the U.S. Department of Health and Human Services and Operation Warp Speed have requested training materials to assist designated sites with the Controlant Onsite Temperature Monitoring Device & Communications Flow. Materials, specifications, and assumptions are subject to change.

How to Return the Box – 2/2

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Are the boxes and loggers ready to be collected

Please confirm whether the boxes and the data loggers inside are ready to be collected by pressing the relevant button below.

| Yes, they are ready to be collected |

| No, I plan to continue to use the box to store my products |

| I'm missing return shipping label |

Email

Phone

Pickup instructions:

Cancel   Update contact info, instructions and submit

3. Select "Yes, they are ready to be collected"

4. Add contact information and pickup instructions

5. Click "Update contact info, instructions, and submit"

6. Follow the Thermal Shipper Return Guidance

[Pfizer Thermal Shipper Return Guidance PDF (Link)](#)

Current as of February 2, 2021, the U.S. Department of Health and Human Services and Operation Warp Speed have requested training materials to assist designated sites with the Controlant Onsite Temperature Monitoring Device & Communications Flow. Materials, specifications, and assumptions are subject to change.

Get a New Shipping Label – 1/2

Subject Line: Onsite monitoring for your vaccines - order #OS – 80#######)
From: onsitemonitoring@controlant.com

Stop onsite monitoring BEFORE returning the box

1. Open email

Onsite monitoring

1 box is being monitored.

Click here to view temperature status,

assign more contacts or stop monitoring

If any of your products in the box(es) referenced below are not released, please make sure to match the boxIDs with the information below and keep the products separate. A follow up email will be sent within 48 hours containing further instructions.

Are the box and data logger ready for collection?

Please confirm whether the box and the data logger inside are ready to be collected, or if you plan to continue to use the box.

Please confirm collection or usage

2. Scroll down and select "Please confirm collection or usage"

Get a New Shipping Label – 2/2

3. Select "I'm missing the return shipping label"

4. Click "Update contact info, instructions, and submit"

Stop onsite monitoring BEFORE returning the box

The screenshot shows:

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Are the boxes and loggers ready to be collected

Please confirm whether the boxes and the data loggers inside are ready to be collected by pressing the relevant button below.

- Yes, they are ready to be collected
- No, I plan to continue to use the box to store my products
- I'm missing return shipping label

Email

Phone

Pickup instructions:

Cancel | Update contact info, instructions and submit

Temperature Alerts (Excursions)

- Temperature alert (excursion) emails
- How to respond to an alert

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Temperature Alert Triggers

Type	Event	Trigger	Message	Outcomes
Normal	First email	Shipment is from Pfizer is delivered and stop button pressed	Onsite monitoring started	• We are using our own freezer and the box is now empty • Other (please specify)
Normal	Daily email	1x reminder email per day	Onsite monitoring status update	• Stop monitoring, the box is now empty • Other (Please specify)
Excursion	Low Severity	> - 70°C for more than 1 hour	Add more dry ice within 12 hours if being used longer	• We will use the box within 3 days from today • We will arrange a re-ice • Stop monitoring, the box is now empty • Other (Please specify)
Excursion	Medium Severity	> - 65°C for more than 1 hour	Add more dry ice ASAP if being used longer	• We will arrange re-ice ASAP • Stop monitoring, the box is now empty • Other (Please specify)
Excursion	High Severity	> - 60°C for more than 1 hour OR > 0°C immediately	Quarantine product and contact Pfizer for guidance as to if product can be used	• We have placed the product in quarantine • Vendor confirmed that the product is suitable for use • Vendor confirmed that the product is not suitable for use • Stop monitoring, the box is now empty • Other (Please specify)
Excursion	High Severity	< -96° C	Quarantine product and contact Pfizer for guidance as to if product can be used	

Respond to Temperature Alert

Onsite monitoring exception

The following logger has a **Temperature Alarm** exception

Logger ID: CMS [Redacted] DO NOT USE INTERNET EXPLORER!

Box ID: USU0 [Redacted]

Onsite ID: OS - 80 [Redacted]

Exception ID: [Redacted]

Click here to respond to the exception and to view the temperature status

Supported browsers are current versions of Chrome, Safari, Firefox and Edge.
If you continue to have issues accessing these links, contact your IT department to confirm they are not blocked by your organization.

1. Open link to respond to temperature alert

If box is empty, you must also deactivate monitoring

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Onsite monitoring exception

The following logger has a **Temperature Alarm** exception

Logger ID: [Redacted]
Box ID: USU [Redacted]

Low
Add more dry-ice within 12 hours if being used longer

Logger	Box ID	Batch #	Qty	Logger Status	Max [°C]	Mean [°C]	Min [°C]
10011383	USU0200030027	5000050524	1	Monitoring	-52.9	-85.0	-89.3

2. Select alert response and submit

logger_id
● 10011383

Choose outcome:

Other	Will use box for less than 3 days
Will arrange re-ice	Stop monitoring, box is now empty

Onsite Monitoring – Low Exception

If a **Temperature Alarm exception** occurs while the products are stored onsite, your designated site contact(s) will receive an email and text message, indicating whether a **Low, Medium, or High** exception has occurred.

1 Click the link in the email to respond to the temperature exception and view the temperature status.

2 The link will take the onsite contact(s) to a status page, which includes information about the level of exception and actions to be taken.

3 If the product has experienced a **Low** exception, **more dry ice should be added to the box within 12 hours** if the products will be stored longer.

4 The site contact must indicate:
1. We will use the box within 3 days from today
2. We will arrange for a re-ice
3. Stop monitoring, the box is empty
4. Other (needs to be specified and captured in the product record)

5 Optionally include a comment in comment box or a file upload to the product record.

6 Click **Submit.**

7 If a site point of contact or their designees are unresponsive (no response within 30 minutes), they will be called by Controlant's call center by telephone to resolve the issue.

DO NOT USE INTERNET EXPLORER!

Subject: Onsite Monitoring: Temperature Alarm for logger CMS 1000F7B6 (OnsiteID:OS - 8091207974; ExceptionID:E1BF4944-0E25-4D5C-A14F-808A58232580)

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Onsite monitoring exception

The following logger has a **Temperature Alarm** exception

Logger ID: CMS 1000F7B6

Box ID: USU0200038821

Onsite ID: OS - 8091207974

Exception ID: E1BF4944-0E25-4D5C-A14F-808A58232580

Click here to respond to the exception and to view the temperature status

Supported browsers are current versions of Chrome, Safari, Firefox and Edge.
If you continue to have issues accessing these links, contact your IT department to confirm they are not blocked by your organization.

Thank you

The Controlant Team
Email: onsitemonitoring@controlant.com
US: +1 (855) 44-CONTROL (+1 (855) 442-6687)
International: +354 517 0630
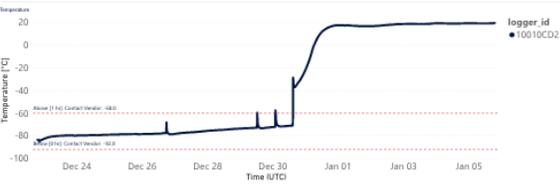
Onsite Monitoring – Medium Exception

If a **Temperature Alarm exception** occurs while the products are stored onsite, your designated site contact(s) will receive an email and text message, indicating whether a **Low, Medium, or High** exception has occurred.

1 Click the link in the email to respond to the temperature exception and view the temperature status.

2 The link will take the onsite contact(s) to a status page, which includes information about the level of exception and actions to be taken.

3 If the product has experienced a **Medium** exception, **more dry ice ice should be added to the box ASAP** if the products will be stored longer.

4 The site contact must indicate:
1. We will arrange for re-ice ASAP
2. Stop monitoring, the box is now empty
3. Other (needs to be specified and captured in the product record)

5 Optionally include a comment in comment box or a file upload to the product record.

6 Click **Submit**.

7 If a site point of contact or their designees are unresponsive (no response within 30 minutes), they will be called by Controlant's call center by telephone to resolve the issue.

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Onsite Monitoring – High Exception

If a **Temperature Alarm exception** occurs while the products are stored onsite, your designated site contact(s) will receive an email and text message, indicating whether a **Low, Medium, or High** exception has occurred.

1 Click the link in the email to respond to the temperature exception and view the temperature status.

2 The link will take the onsite contact(s) to a status page, which includes information about the level of exception and actions to be taken.

3 If the product has experienced a **High** exception, **the products must be quarantined and vendor contacted for guidance as to whether product may be used.**

4 The site contact must indicate:
1. We have placed the product in quarantine
2. Vendor confirmed that the product is suitable for use
3. Vendor confirmed that the product is not suitable for use
4. Stop monitoring, the box is now empty
5. Other (needs to be specified and captured in the product record)

5 Optionally include a comment in comment box or a file upload to the product record.

6 Click **Submit.**

7 If a site point of contact or their designees are unresponsive (no response within 30 minutes), they will be called by Controlant's call center by telephone to resolve the issue.

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Manual Data Upload & Logger Charging

- How to manually upload data to Controlant
- How to charge the logger's battery

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Upload Data to Controlant

If your logger has poor or no cell service, you must upload data manually

1. Pull out the hidden USB connector in the logger device
   - DO NOT DISCONNECT THE TEMPERATURE PROBE!
2. Connect logger device to your PC or Mac
3. Open https://upload.controlant.com/
4. Upload DATA.BIN file from logger device
5. Wait 15 minutes
6. Confirm successful upload by opening the onsite monitoring link for the box
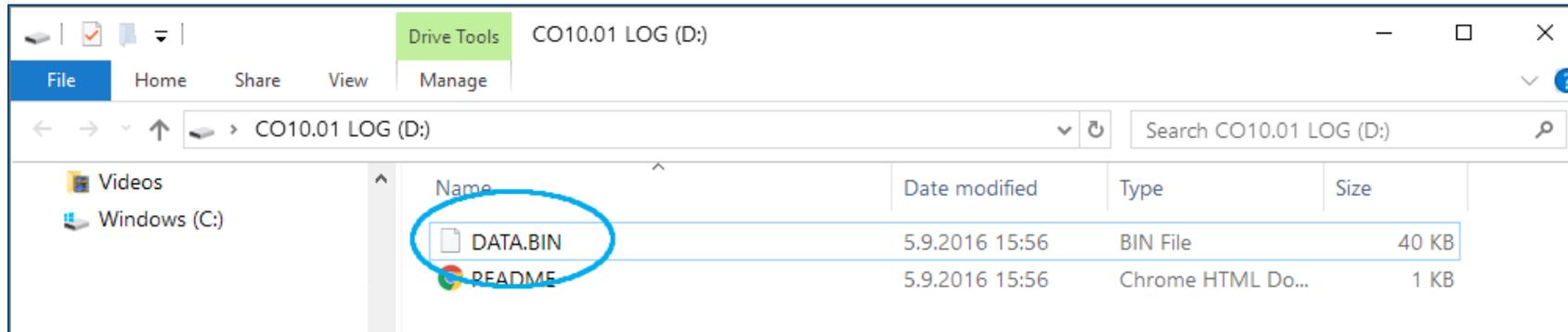
Recharge Logger Battery

If your logger has low battery, follow these instructions to recharge

1. Pull out the hidden USB connector in the logger device
   - DO NOT DISCONNECT THE TEMPERATURE PROBE!
2. Connect logger device to your PC, Mac, or outlet using the USB connection
3. Wait 30 minutes

IT & Access Issues

- Email & access issues
- Browser issues

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Email and Access Issues

You must be able to receive emails from these addresses to receive shipment and onsite monitoring alerts.

You require access to these domains to access onsite monitoring links.

Controlant Email Addresses
@controlant.com
onsitemonitoring@controlant.com
usgov.projects@controlant.com
reports@controlant.com
pfizer.logistics@controlant.com
call-center@controlant.com
reverse.logistics@controlant.com

Controlant Domains
https://controlant.com
https://.ct.sendgrid.net
https://modalforms.controlant.com
https://eur02.safelinks.protection.outlook.com
https://usg.bi.controlant.info
https://api.controlant.info
https://dc.services.visualstudio.com
https://wabi-north-europe-redirect.analysis.windows.net

Browser Issues

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https://modalforms.controlant.com/onsitemonitoring?eventlogid=CDE4FEBD-F41A-42D6-B5DA-B6E9A14E69CB&sid=

BGF
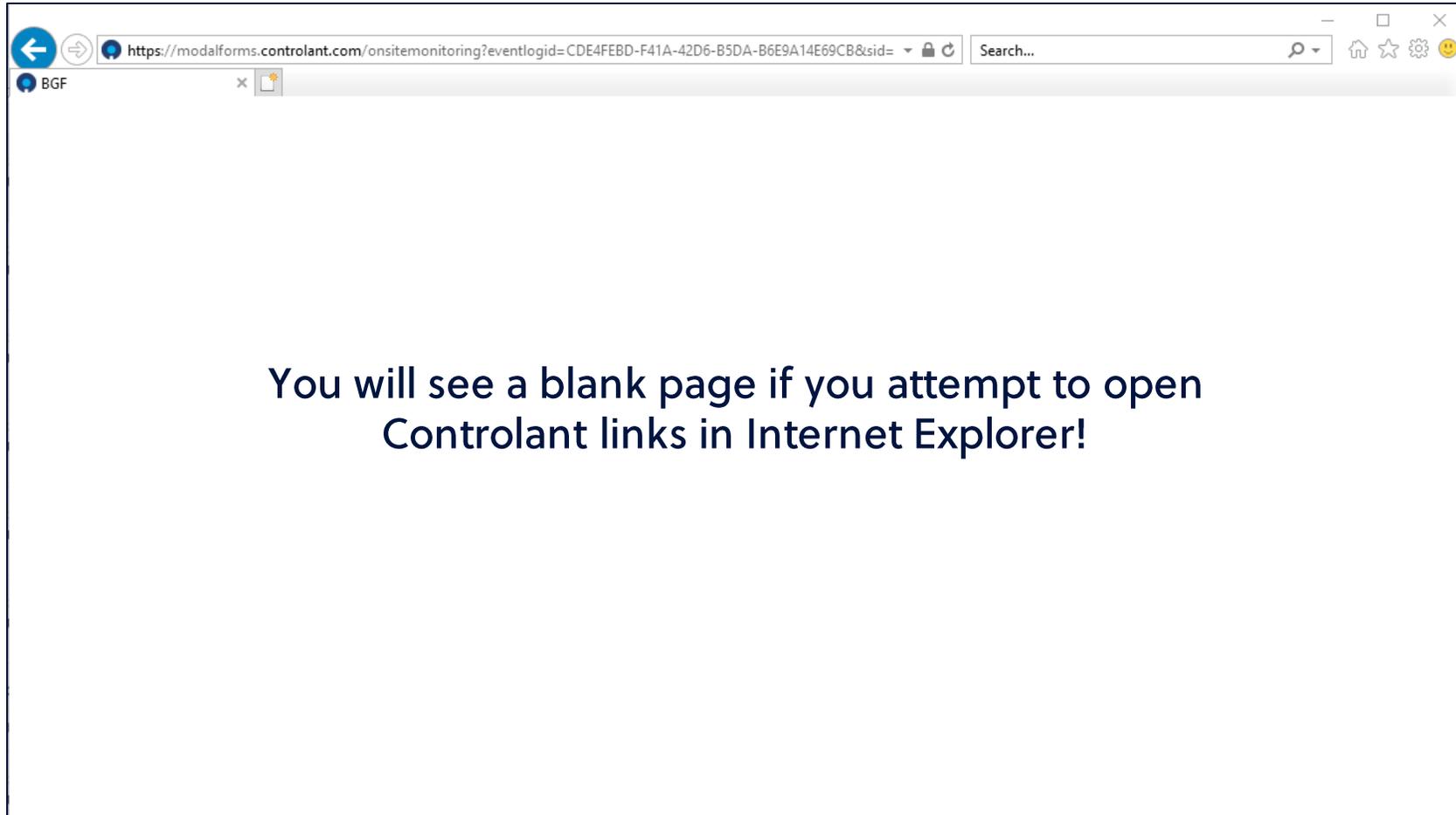
You will see a blank page if you attempt to open Controlant links in Internet Explorer!

Use one of these browsers instead:
- Chrome
- Firefox
- Safari
- Edge

Frequently Asked Questions

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FAQs

- Can we redistribute the Controlant boxes to other sites?
  - No. Controlant only supports monitoring to the original shipment location. You are responsible for storage and monitoring beyond that location.

- Can we keep the Controlant boxes for non-vaccine storage?
  - No. Please return the boxes as soon as you are done using them for vaccine storage so that we may

- How do we stop dry ice refills?
  - Controlant does not manage dry ice refills. Contact the dry ice vendor to stop deliveries.

Contact Support

- How to get help

Controlant

Additional Support

Contact	Contact Information	Purpose
24/7 support hotline	1-855-442-6687 OR 1-701-540-4039	Call for 24/7 questions or issues
24/7 support email	support@controlant.com	Contact for 24/7 questions or issues
Onsite monitoring support	onsitemonitoring@controlant.com	Contact for onsite monitoring support
Pfizer Medical Information	www.PfizerMedInfo.com 1-800-438-1985	Consult for questions about the Pfizer BioNTech COVID-19 vaccine
State Immunization Program Managers	Find your State Immunization Program Manager here: https://www.immunizationmanagers.org/page/MemPage	Change your default point of contact in VTRCKS

Communication Procedures

Only contact Controlant through your POC email address (work email).

The following actions **must be performed by the Point of Contact and cannot be performed via phone call**. These processes are in place to ensure security.

1.   Opting out of all onsite monitoring for a site

2.   Adding additional contacts for onsite monitoring

Controlant will not provide access to temperature data to unauthorized individuals.