UN SYSTEM-WIDE COVID-19 VACCINATION PROGRAMME

STORAGE, HANDLING AND TRANSPORTATION OF MODERNA VACCINE

VERSION 3 – 18 FEBRUARY 2022

BACKGROUND

1. The UN System-wide COVID-19 Vaccination Programme is receiving a donation of Moderna (mRNA-1273) vaccines, which is being allocated to Local Vaccine Deployment Teams for administration as primary vaccination series (first, second, and/or additional doses where applicable) and booster doses, for eligible individuals as indicated in the Eligibility Document[1].

2. The Moderna COVID-19 Vaccine is a suspension for intramuscular injection. The vaccine donated to the Programme is from lot number 038F21A, which **expires on 01 April 2022** (the "Expiration Date"). It is supplied in 7.5mL multiple-dose vials. An average of 14 full doses (range: 13-15 doses) may be extracted from each vial. Each carton includes 10 vials.

3. The vaccine is stored frozen at -50ºC to -15ºC. It will be shipped frozen from the central warehouse to the countries. Once thawed, the vials can be stored at 2° to 8°C for up to 30 days.

4. Whether kept in frozen or thawed condition, the vaccine **should not be used past their Expiration Date** on 01 April 2022.

5. Upon reaching expiration date, all unused vials must be discarded following appropriate protocols outlined in this document.

UNMD GUIDANCE ON ADMINISTRATION OF MODERNA VACCINE

6. The UN Medical Directors' Network (UNMD) has issued recommendations for the utilization of Moderna vaccine under the Programme. The guidance document is available on the Programme's website: https://www.un.org/sites/un2.un.org/files/unmd_recommendations_for_moderna_booster_vaccine_for_un_vaccination_programme.pdf

7. The guidance document addresses the administration of Moderna vaccines as part of primary immunization schedules and as boosters, either homologous (same vaccine type) or heterologous (mixed vaccine types). It specifies the dosage (full dose 0.5mL [100 micrograms] or half dose 0.25mL [50 micrograms]) and time interval applicable to each scenario.

[1] https://www.un.org/sites/un2.un.org/files/un_system-wide_covid-19_vaccination_programme_-_eligibility.pdf

STORAGE AND HANDLING

8. The FDA-approved recommendations on storage and handling of Moderna vaccines are published on Moderna's website:
   https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling

9. Moderna COVID-19 Vaccine multiple-dose vials are **stored frozen between -50º to -15ºC**. Vials should be stored in the original carton to protect them from light. Do not store on dry ice or below -50ºC.

10. Once thawed, the Moderna COVID-19 Vaccine **can be stored refrigerated between 2° to 8°C for up to 30 days**. Do not refreeze once thawed.
    Note: In any case, the batch Expiration Date (01 April 2022, inclusive) is the limit to administer doses, even if a particular vial was thawed less than 30 days prior.

11. Unpunctured vials may be stored at room temperature between 8° to 25°C **for up to 24 hours**. After the first dose has been withdrawn, the vial should be held between 2° to 25°C. Vials should be discarded 12 hours after the first puncture. Thawed vials can be handled in room light conditions. Do not refreeze once thawed.

LIMIT OF 20 PUNCTURES PER VIAL

12. When extracting only booster doses or a combination of primary series and booster doses, the maximum number of doses that may be extracted from each vial should **not exceed 20 doses**. Do not puncture the vial stopper more than 20 times. If the vial stopper has been punctured 20 times, discard the vial and contents.

GUIDELINES FOR THAWING BEFORE ADMINISTRATION

13. Thawing in refrigerated conditions: Thaw 7.5mL vials between 2° to 8°C for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.

14. Alternatively, thaw 7.5mL vials at room temperature between 15° to 25°C for 1 hour and 30 minutes.

VACCINE ADMINISTRATION

INSPECTION

15. Prior to administration, vials should always be inspected to confirm that liquid is white to off-white. Vaccine may contain white or translucent product related particulates.

16. Swirl vial gently after thawing and before each withdrawal. The vaccine comes ready to use once thawed. **Do not shake or dilute**.

17. Prior to injection inspect each dose to confirm liquid is white to off-white in colour in both vial and syringe, and verify syringe volume. If dosage is incorrect or discolouration or other particulate matter is present, do not administer the vaccine.

TYPES OF NEEDLES

18. The Moderna vaccine is a suspension for intramuscular (IM) injection. IM needles should be used for inoculation.
    Note: Certain types of syringes delivered under the Programme have smaller, subcutaneous needles pre-mounted. These smaller needles can be used to prepare the vaccine dose but are not

recommended for intramuscular injection. They should be replaced with the IM ones prior to inoculation. In that case, please use the IM needles 23Gx1" (0.60 x 25mm) provided in their own packages, separate from the syringes.

MINIMIZING CORING

19. In order to minimize the risk of breaking off small pieces of the rubber stopper into the liquid when puncturing the vial, it is recommended to insert the needle within the target ring, at a 45–60° angle, with the opening of the needle tip facing up (i.e., away from the stopper). A small amount of pressure is applied and the angle is gradually increased as the needle enters the vial. The needle should be at a 90° angle just as the needle bevel passes through the stopper.

TRANSPORTATION

20. A carton of Moderna COVID-19 Vaccine contains 10 multiple-dose vials. The dimensions of a carton of vaccine are 5.4" x 2.1" x 2.4" (approx. 13.8cm x 5.4cm x 6.1 cm).

21. Moderna vaccines should be transported in the frozen state at -50°C to -15°C.

22. If transport at -50° to -15°C is not feasible, transportation of thawed vials for up to 12 hours at 2° to 8°C is acceptable, when shipped using shipping containers which have been qualified to maintain 2° to 8°C and under routine road and air transport conditions with shaking and vibration minimized. Once thawed and transported at 2° to 8°C, vials should not be refrozen and should be stored at 2° to 8°C until use. Once thawed, the vaccine must be used within 30 days as per Para 10 above.

23. The thermal boxes used by the Programme to ship vaccines to the destination countries, both at -50°C to -15°C and at 2° to 8°C (in previous shipments of other vaccine types), **may be re-used** for transportation within the country, provided that they have not been damaged during transit. Please follow the applicable SOP for **pre-conditioning the cooling elements (in advance)** and loading them in the box at packing (see Annex 2 and Annex 3).

FROZEN OR COLD STORAGE CAPACITY AT THE COUNTRY LEVEL, POSSIBLE SCENARIOS

24. Moderna vaccines will be shipped frozen at -50°C to -15°C from the central warehouse in Denmark to the destination countries.

25. If local teams have the capacity to store the Moderna vaccines frozen at -50°C to -15°C, they should do so. They can handle the thawing process of individual vials on a continuous basis, in accordance with the pace of the vaccination campaign, and administer doses until the expiration date on 01 April 2022.

26. If local teams do not have the capacity to store the Moderna vaccines frozen, then they should thaw the vials in refrigerated conditions at 2°C to 8°C upon receipt. Vials can then be stored at 2°C to 8°C for up to 30 days prior to first use (or the Expiration Date on 01 April 2022, whichever comes first). In this scenario, local teams may wish to request staggered shipments from the central warehouse to be able to administer vaccines until the Expiration Date. Two shipments would be required in case primary immunization schedules are being offered, with 28 days in between the two doses.

27. Below is an illustration of how country teams with different storage capacities may organize their vaccination drive with the Moderna vaccine:

Country team scenarios (local storage capacity)	Scenario 1: Country team with frozen storage capacity (-50°C to -15°C)	Scenario 2: Country team with cold/refrigerated storage capacity (2°C to 8°C)
Shipment from central warehouse	Frozen at -50°C to -15°C	Frozen at -50°C to -15°C
Vaccine receipt	Vials to be stored frozen at -50°C to -15°C, kept in original cartons to protect from light.	Frozen vials to be thawed in refrigerated conditions at 2°C to 8°C upon receipt. Vials can stay in cartons at 2°C to 8°C.
Storage	Frozen vials: until the Expiration Date. Thawed vials to be stored at 2°C to 8°C degrees for up to 30 days from the day of thawing.	Thawed vials to be stored at 2°C to 8°C degrees for up to 30 days from receipt of the shipment.
Thawing	In a phased manner: for administration or for in-country transportation at 2°C to 8°C. For each vial, the thawing date should be duly recorded.	N/A (all vials thawed upon receipt)
In-country transportation	At -50°C to -15°C if possible. If not, at 2°C to 8°C for up to 12 hrs.	At 2°C to 8°C for up to 12 hrs.
Possible delivery approach	**Country team to receive all Moderna vaccines from the Programme in one go and handle the thawing of vials as part of the local campaign until 01 April.**	**Country team may request staggered delivery from the Programme (two consecutive shipments from the central warehouse), to ensure continuity of usable supply until the Expiration Date on 01 April.**

INFORMATION TO VACCINE RECIPIENTS, PHARMACOVIGILANCE, REPORTING OF ADVERSE EVENTS

28. Vaccine recipient must be provided information consistent with the factsheet[2] prior to receiving each dose of vaccine including benefits/risks of vaccination. Vaccine recipients must be provided with adverse event reporting instructions.

29. Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine. See DHMOSH guidance[3] for reference.

30. Adverse events following vaccination that are beyond the normal side effect profile and require treatment are to be recorded as part of the clinic visit for that vaccination in Everbridge. The UN has an obligation to cooperate with the manufacturer with respect to pharmacovigilance and the occurrence of adverse events and safety reports in the administration of the Moderna COVID-19 Vaccine under the Programme.

EVERBRIDGE

31. The Everbridge platform has been updated to allow the recording of individuals' additional doses. The Moderna vaccine type, applicable batch number and two authorized dosages (0.5mL and 0.25mL) have been added to the platform. Please ensure the Medical Personnel records the right dosage in Everbridge, as applicable. Changes have been made to the platform to allow for all medical personal within a country to be able to update the records of the vaccine candidate across the clinics within the country.

[2] https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf
[3] https://www.un.org/sites/un2.un.org/files/coronavirus_vaccination_anaphylaxisguidelines.pdf

32. Further guidance will be published in due course with respect to additional enhancements that are being developed (e.g., "walk-in clinic" functionality) to improve the useability of the platform for local teams, improving visibility and flexibility.

DESTRUCTION OF USED, EXPIRED OR UNUSABLE VIALS, AND ANCILLARIES

33. Used COVID-19 vaccine vials and ancillary supply should be disposed of according to medical waste management best practices. See guidance here for reference: https://www.afro.who.int/sites/default/files/2021-05/SOP%20Waste%20management%20of%20Covid-19%20Vaccines%20%281%29.pdf

34. Unused vials: Any vial of vaccine that exceeds the shelf life indicated by the manufacturer should be disposed of as **regulated medical waste**.

35. The manufacturer recommends the incineration of all unusable vials (e.g., depleted, empty, expired, defective or contaminated vaccine vials) and packaging, wherever possible, in a manner similar to medical waste, in accordance with applicable law and regulation. To the extent such incineration is not available or possible, such vials and packaging must be defaced or safely crushed so that they cannot be reintroduced or reproduced. Once sufficiently defaced, they must be disposed of in accordance with applicable law and regulation.

36. Certificates of destruction must be issued and collected by each local vaccine deployment team. Upon expiration of the vaccine batch, a record of all destructions of expired or otherwise unusable vaccines must be provided to the to the Global Vaccine Deployment Support Team (GVDST) via email to covidvaccines@un.org. The GVDST will provide the manufacturer with written confirmation of the destruction or disposition of such unused vaccines.

ADDITIONAL RESOURCES

The manufacturer's storage/handling guidance, the fact sheet to vaccine providers and full Emergency Use Authorization (EUA) by the US Food and Drug Administration are available at: https://www.modernatx.com/covid19vaccine-eua/providers/storage-handling.pdf

A short video on storage and handling of Moderna vaccine is available at: https://youtu.be/8kq6-U5bckI

Temperature excursion tool: If you believe some vials have experienced a temperature excursion, you may use Moderna's Temperature Excursion Tool for further instructions: https://tools.modernamedinfo.com/en-US/excursion/introduction-landing-page

Vial puncture tracker: https://www.modernatx.com/covid19vaccine-eua/providers/vial-dose-tracker.pdf

You may also contact the GVDST for additional guidance at covidvaccines@un.org.

ANNEXES

- Annex 1: Manufacturer's synopsis on storage and handling.
- Annex 2: SOP on pre-conditioning cooling elements (Va-Q-Pads type -21G) for transportation at -50°C to -15°C
- Annex 3: SOPs on pre-conditioning cooling elements (Va-Q-Pads type +05G) for transportation at 2°C to 8°C

Annex 1 – Manufacturer's synopsis on storage and handling

Frozen Storage

Can be stored frozen until expiration date*

–50° to –15°C (–58° to 5°F)

Do not store on dry ice or below -50°C (-58°F).
Store in the original carton to protect from light.

*Confirm vaccine expiration date by looking up the lot number at modernatx.com/covid19vaccine-eua

Thaw Each Vial Before Use

Vial images for illustrative purposes only

Refrigerator
5.5 mL vials: 2 hours 30 minutes
7.5 mL vials: 3 hours

2° to 8°C
(36° to 46°F)

OR

Room temperature
5.5 mL vials: 1 hour
7.5 mL vials: 1 hour 30 minutes

15° to 25°C
(59° to 77°F)

Let vial sit at room temperature for 15 minutes before administering

Thawed Shelf Life

Unpunctured Vial

Maximum times

30 days — Refrigerator: 2° to 8°C (36° to 46°F)

24 hours — Cool storage up to room temperature: 8° to 25°C (46° to 77°F)

After First Dose Has Been Withdrawn

Maximum time

12 hours — Refrigerator or room temperature

Vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the vial label.

Discard punctured vial after 12 hours.

NEVER **refreeze thawed vaccine**

The maximum number of times a vial stopper can be punctured is 20.

Annex 2 – SOP on pre-conditioning cooling elements for transportation at -50°C to -15°C

Keep Va-Q-Pads (**type -21G**) at -25°C for at least 72 hrs.

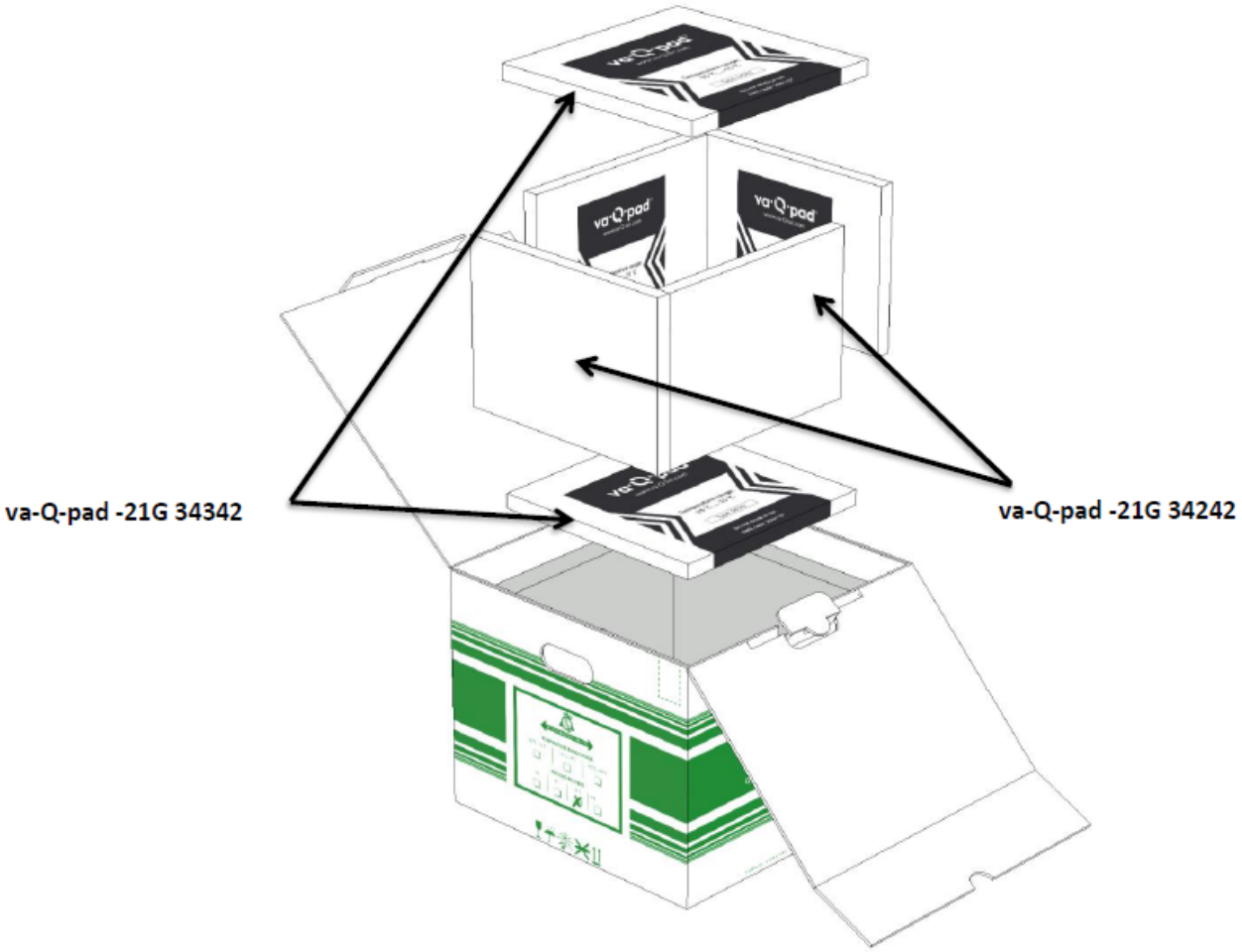
va-Q-tec
ALWAYS THE RIGHT TEMPERATURE

3.4 PCM, container and good pre-conditioning

Table 12: Pre-conditioning Data

PCM pre-conditioning	PCM-Type	Temperature	Duration
	-21G	≤-25.0°C	≥72 hrs
Good pre-conditioning	**Good**	**Temperature**	**Duration**
	va-Q-gel 48 M	-20.0 °C ±0.5 °C	≥72 hrs

3.5 va-Q-pad and good loading



Annex 3 – SOPs Preconditioning cooling elements (Va-Q-Tec) for 2°C to 8°C shipments

OPTION 1: Keep Va-Q-Pads (**type +05G**) at 3°C for at least 72 hrs.

va-Q-tec AG
Alfred-Nobel-Straße 33
D-97080 Würzburg
Tel: +49 (0)931 35 942 -0
www.va-Q-tec.com

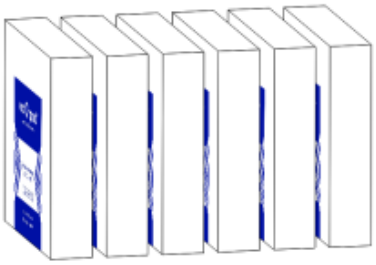
va-Q-tec
ALWAYS THE RIGHT TEMPERATURE

SOP: Preconditioning va-Q-pads for va-Q-one 4, va-Q-one 8, va-Q-one 23 and va-Q-one 43 for +2 °C to +8 °C shipments

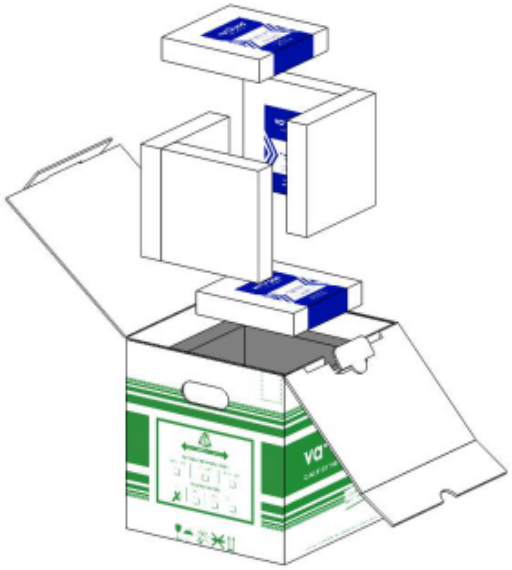
PCM type +05G (color code: blue)

Step 1
Place the va-Q-pads (short "pads") in a row with the distance of approximately 15 mm to each other.

Store the pad bundles in a cool room at a temperature of +3.0 ± 0.5 °C for at least 72 hours.



Step 2
Load the pads into the box as per the respective Loading SOP instructions.



OPTION 2: Keep Va-Q-Pads (**type +05G**) at -20°C for at least 24 hrs. then at 2°C to 8°C for 9 hrs.

va-Q-tec AG
Alfred-Nobel-Straße 33
D-97080 Würzburg
Tel: +49 (0)931 35 942 -0
www.va-Q-tec.com

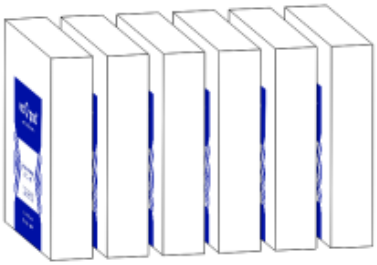
ALWAYS THE RIGHT TEMPERATURE

SOP: Preconditioning va-Q-pads for va-Q-one 4 for +2 °C to +8 °C shipments

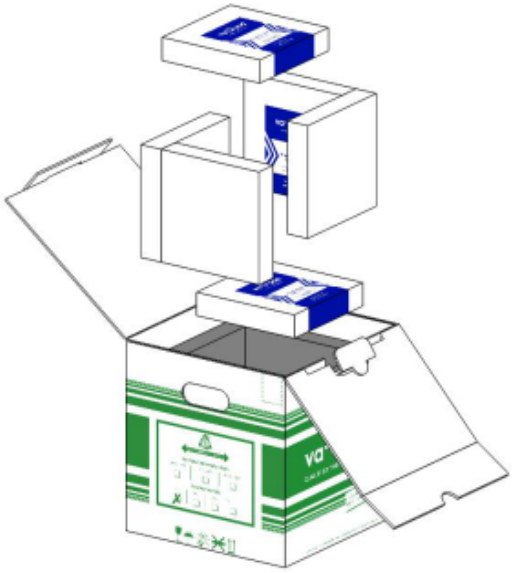
va-Q-pad size 20204 with PCM type +05G (color code: blue)

Step 1
Place the va-Q-pads (short "pads") in a row with the distance of approximately 15 mm to each other.

Store the pad bundles in a freezer at a freezer temperature of -20.0 ± 5 °C for at least 24 hours.



Step 2
Take the pads out of the freezer and store the pads in a cool room at +5 ± 3°C for 9 ± 1 hours.



Step 3
Load the pads into the va-Q-one 4 as per the respective Loading SOP instructions.