

IMMULITE® 2000/XPi

Probe Cleaning Kit

PROBE CLEAN



Revision bar indicates update to previous version.

Intended Use

For use in daily maintenance of the IMMULITE® 2000/XPi Systems - to minimize reagent carryover by reducing protein and lipid buildup in the probes.

PHÓ GIÁM ĐỐC
TỔNG THỊ BÍCH TUYẾN

Reagents

Reagent	Description	Storage	Stability
IMMULITE® 2000/XPi Probe Cleaning Kit PROBE CLEAN			
PROBE CLEAN SOL	Ready to use liquid containing: • Sodium hypochlorite solution (< 4.4 %)	15–28 °C May be used up to the expiry date indicated on the label if stored unopened.	n/a
WEDGE			n/a

Promptly replace the cap on the **PROBE CLEAN SOL** bottle (black plastic bottle) and tighten the cap securely once the required material for cleaning has been removed.

WEDGE: Open and reusable wedge.

The **WEDGE** is required only for the Probe Cleaning procedure with software version 5.3b and below.

Warnings and Precautions

- For *in-vitro* diagnostic use only.
- For laboratory professional use.
- According to EU regulation 2017/746, any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or patient is established.
- Safety data sheets (MSDS/SDS) available on siemens-healthineers.com/sds.



Danger! **PROBE CLEAN SOL**

Hazardous ingredient: Sodium hypochlorite solution (4 % [w/w]).
H290: May be corrosive to metals. **H314:** Causes severe skin burns and eye damage. **H400:** Very toxic to aquatic life. **H411:** Toxic to aquatic life with long lasting effects.
P280: Wear protective gloves/protective clothing/eye protection/face protection. **P234:** Keep only in original container. **P264:** Wash hands thoroughly after handling. **P273:** Avoid release to the environment. **P301 + P330 + P331:** IF SWALLOWED: rinse mouth. Do NOT induce vomiting. **P303 + P361 + P353:** IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. **P305 + P351 + P338:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. **P310:** Immediately call a POISON CENTER or doctor/physician. **P390:** Absorb spillage to prevent material damage. **P391:** Collect spillage. **P501:** Dispose of contents and container in accordance with all local, regional, and national regulations.

Alkaline material. Contains bleach. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Avoid ingestion. Requires general open-room ventilation.

Do not use Probe Cleaning Solution (LPMS) in place of Probe Wash (L2PWS2).

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with all government requirements.

Procedure

Materials Provided

REF	Contents	
L2KPM	IMMULITE® 2000/XPi Probe Cleaning Kit	
	PROBE CLEAN	
	IMMULITE® Probe Cleaning Solution (LPMS)	100 mL
	PROBE CLEAN SOL	
	Probe Cleaning Wedge (L2PCW)	1 pc.
	WEDGE	
	Probe Cleaning Barcode ^a	30 pcs.

^a Barcodes for use on IMMULITE® 2000 XPi System only.

Materials Required but not Provided

Item	Description
–	Distilled or deionized water without preservatives
–	2 mL pipet
–	12x 75 mm sample tube
Instruments ^b , such as:	<ul style="list-style-type: none"> • IMMULITE® 2000 System • IMMULITE® 2000 XPi System

^b Availability of analyzers may vary by country.

Daily Cleaning Procedure

NOTE: This procedure applies to software version 5.4 and above.

1. Pipet 1.5 mL of Probe Cleaning Solution into a 12 x 75 mm sample tube.
2. Place the sample tube in position 1 of any sample rack. Place the sample rack in position 1 of the Sample Carousel.
3. Double-click on the **Diagnostics** icon.
4. Click on the **Condensed Run Program** button.
5. Select **Daily Probe Cleaning**, click on **RUN**, and follow the prompts.

6. When the 10-minute procedure is complete, click on **Exit**.
7. Click on **Quit**.
8. Remove the sample tube and discard the remaining solution.
9. Double-click on the **IMMULITE 2000** or **IMMULITE 2000 XPi** icon to resume normal operation.

NOTE: This procedure applies to software version 6.0 and above, when using the AutoStart feature on IMMULITE® 2000 XPi System only.

Prior to each scheduled or manual AutoStart:

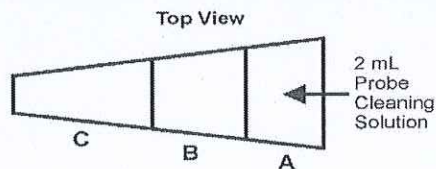
1. Pipet 1.5 mL of Probe Cleaning Solution into a 12 x 75 mm sample tube.
2. Place a Probe Cleaning Barcode onto the sample tube and place the tube into a sample rack. The rack then may be loaded into any position of the Sample Carousel.

Once AutoStart completes:

3. Click **OK** to return to the user software.
4. Eject the sample rack, remove the sample tube, and discard the remaining solution.
5. At this point, resume normal operation.

NOTE: This procedure applies to software version 5.3b and below.

1. Pipet 2 mL of Probe Cleaning Solution into Compartment A of the Probe Cleaning Wedge (see diagram).



2. Pipet 2 mL of Probe Cleaning Solution into a 12 x 75 mm sample tube.
3. Place the Probe Cleaning Wedge in position 1 of the Reagent Carousel.
4. Place the sample tube in position 1 of any sample rack. Place the sample rack in position 1 of the Sample Carousel.
5. Double-click on the **Diagnostics** icon.
6. Click on the **Condensed Run Program** button.
7. Select **Daily Probe Cleaning**, click on **RUN**, and follow the prompts.
8. When the 10-minute procedure is complete, click on **Exit**.
9. Click on **Quit**.
10. Remove the Probe Cleaning Wedge, discard the solution remaining in the Wedge, and rinse the Wedge with distilled or deionized water. Place the Wedge back into the kit for reuse.
11. Double-click on the **IMMULITE 2000** or **IMMULITE 2000 XPi** icon to resume normal operation.
















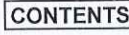



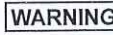


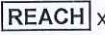
Technical Assistance

Outside the United States, contact your National Distributor.

The Quality System of Siemens Healthcare Diagnostics Products GmbH is certified to ISO 13485.

Definition of Symbols

The following symbols may appear on the product labeling:


	Do not reuse		Use By
	Batch Code		Catalogue Number
	Caution		Manufacturer
	Authorized representative in the European Community		Contains sufficient for <n> tests
	Biological Risks		<i>In Vitro</i> Diagnostic Medical Device
	Temperature Limitation		Consult instruction for Use
	Non-sterile		CE marking of conformity
	CE marking of conformity with notified body ID number. Notified body ID number can vary.		Contents
	Reconstitution volume		Level
	Keep away from sunlight and heat		Warning
	Danger	RxOnly	Prescription device (US only)
	Device Identification (UDI) barcode		REACH Authorization Number xx/xx/xx



Legal Information

IMMULITE is a trademark of Siemens Healthineers.
 All other trademarks are the property of their respective owners.
 © Siemens Healthineers, 2010–2021. All rights reserved.

Siemens Healthineers Headquarters
 Siemens Healthcare GmbH
 Henkestraße 127
 91052 Erlangen
 Germany
 Phone: +49 9131 84-0
 siemens-healthineers.com

 **Siemens Healthcare Diagnostics Products GmbH**
 Emil-von-Behring-Str. 76
 35041 Marburg
 Germany
 siemens-healthineers.com