

IMPORTANT PRODUCT NOTICE

30-June2023

RE: Cleaning and disinfection change for BiPAP A40 Pro, BiPAP A40 EFL, BiPAP A30 EFL and the System One Humidifier for the removal of Keredusy as a disinfection method.

Dear Customer,

Philips Respironics has updated the Instructions for Use (IFU) for A40 Pro, BiPAP A40 EFL, BiPAP A30 EFL and the System One humidifier cleaning to remove Keredusy as a disinfection method.

This Important Product Notice is intended to inform you about:

1. The reason for these changes to the IFU and labeling

There is an update to the Instructions for Use (IFU) for the labeling of this device. Keredusy has been removed as a disinfection method due to unknown long-term effects of this disinfection method on the device components.

This issue does not present any hazard/harm. No adverse events, including death or injuries, have been reported.

2. Affected products and how to identify them

BiPAP A40 Pro, BiPAP A40 EFL, BiPAP A30 EFL, A-Series System One humidifier and Q-series System One humidifier.

3. The actions that you as a customer can take to minimize the effect of the changes

Please refer to the attached A40/A30 IFU addendum with revisions to the cleaning and disinfection methods as well as the updated product warranty coverage.

For the System One humidifier, please refer to the attached IFU with revisions to the cleaning and disinfection method and updated product warranty coverage.

4. The actions planned by Philips Respironics

Philips has updated the BiPAP A40 Pro, BiPAP A40 EFL, BiPAP A30 EFL, and System One humidifier IFU (attached to this letter).

The next revisions to the A40/A30 IFUs will incorporate the information provided in the attached addendums.

5. Additional Information and Support

If you need any further information or support concerning this issue, please contact your local Philips representative: 1-(877)-387-3311 or email at patientsupport@philips.com.

Philips regrets any inconvenience caused by this change.

Sincerely,

Michael Mizrachi

Michael Mizrachi
Head of Quality
Hospital Respiratory Care

Attachment: Affected Devices

BIPAP A40 Pro, BIPAP A40 EFL, BIPAP A30 EFL, System One Humidifier					
1056209	AUX3100S19	CN267TS	ESX3100T19	GBX3H	ITX3000H21
1056210	BLX3000H19	CN467TS	ESX3H	GBX3T	ITX3000S21
1056212	BLX3000S10	CN567TS	ESX3T	HL6H	ITX3000T21
1056215	BLX3000T19	CN667TS	FI6H	HL6HFLG	ITX3100H21
1056216	BLX3100S19	CN767TS	FI6T	HL6T	ITX3100S21
1077107	BLX3H	CNV207H	FR1056210	HL6TFLG	ITX3100T21
1096124	BLX3T	CNV207HN1	FR1111555	IAX3000H19	ITX3H
1111146	BRX3000S18	CNV507H	FR6H	IAX3000S19	ITX3T
1111148	BRX3100S18	CNV507HN1	FR6T	IAX3000T19	NDX3000H19
1111172	CA221NTS	DE6H	FRX3000H14	IAX3100H19	NDX3000S19
1111174	CA261HS	DEX2900S13	FRX3000S14	IAX3100S19	NDX3000T19
1111552	CA261NTS	DEX3000S13	FRX3000T14	IAX3100T19	NDX3100H19
1111555	CA261TS	DEX3100S13	FRX3100H14	IN6H	NDX3100S19
1120348	CA521HS	DEX3H	FRX3100S14	IN6HFLG	NDX3100T19
1120349	CA521NTS	DEX3T	FRX3100T14	IN6T	NDX3H
1147249	CA521TS	EEX3000S19	FRX3H	IN6TFLG	NDX3T
AC1056209	CA961HS	EEX3100S19	FRX3T	INDV501H	NO6H
ARX3000S19	CA961NTS	ES6H	GB6H	INX3000H19	NO6T
ARX3100S19	CA961XTS	ES6HXS	GB6T	INX3000S19	PT6H
AU461HS	CAV201H	ES6T	GBX3000H19	INX3000T19	PT6T
AU461TS	CAV501H	ESX3000H19	GBX3000S19	INX3100H19	RBR1056210
AU561TS	CAX3000S12	ESX3000S19	GBX3000T19	INX3100S19	SE6H
AUV201H	CAX3000T12	ESX3000T19	GBX3100H19	INX3100T19	SE6T
AUV501H	CAX3100S12	ESX3100H19	GBX3100S19	INX3H	SPX3100S19
AUX3000S19	CAX3100T12	ESX3100S19	GBX3100T19	INX3T	UO1056209
				IT1111552	ZA6H