



CALIFORNIA DEVICE RECALL INFORMATION SHEET

NOXBOX LTD NOxBOXi for Malfunctions Due to Misalignment

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|-------------|------------------------------------|-------------------------------|---|
| 6/21/2023 | NOxBOXi Product1 details | NOXBOX LTD Location | Device may experience malfunctions due to misalignment of the check valve in the manifold. If the device fails, there is a risk of nitric oxide leak, oxygen gas leak, or earlier cylinder gas changeover than expected or not at all. In a worst-case scenario, there may be an interruption in therapy which could lead to oxygen desaturation of the patient and associated complications. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|--------------|---|---------------------------|-----------------------|
| I | NOxBOXi UDI/DI: 5060541640009 Serial Numbers distributed in US: NI101029 NI102476 NI102518 NI102560 NI102594 NI102629 NI101388 NI102477 NI102519 NI102561 NI102595 NI102630 NI101392 NI102478 NI102520 NI102562 NI102596 NI102631 NI101441 NI102479 NI102522 NI102563 NI102597 NI102632 | 11 Units in California | May 2023 and Prior |

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| NI101562 NI102480 NI102525 NI102564 NI102598 NI102633 NI101679 NI102481 NI102528 NI102565 NI102599 NI102634 NI101703 NI102482 NI102530 NI102567 NI102600 NI102635 NI101760 NI102483 NI102531 NI102569 NI102601 NI102636 NI101806 NI102484 NI102535 NI102571 NI102602 NI102637 NI101881 NI102485 NI102537 NI102573 NI102604 NI102639 NI101927 NI102486 NI102538 NI102574 NI102605 NI102640 NI102024 NI102487 NI102539 NI102575 NI102606 NI102641 NI102097 NI102493 NI102540 NI102576 NI102608 NI102642 NI102111 NI102495 NI102541 NI102577 NI102610 NI102646 NI102193 NI102496 NI102542 NI102578 NI102611 NI102647 NI102255 NI102497 NI102544 NI102579 NI102613 NI102649 NI102311 NI102498 NI102545 NI102580 NI102614 NI102652 NI102394 NI102499 NI102546 NI102581 NI102615 NI102654 NI102397 NI102500 NI102547 NI102582 NI102616 NI102655 NI102398 NI102502 NI102548 NI102583 NI102617 NI102656 NI102436 NI102504 NI102550 NI102584 NI102618 NI102657 NI102438 NI102506 NI102551 NI102585 NI102619 NI102658 NI102444 NI102509 NI102552 NI102586 NI102620 NI102659 NI102445 NI102510 NI102553 NI102587 NI102621 NI102660 NI102463 NI102511 NI102554 NI102588 NI102622 NI102661 NI102466 NI102512 NI102555 NI102589 NI102623 NI102662 NI102467 NI102513 NI102556 NI102590 NI102625 NI102663 NI102473 NI102514 NI102557 NI102591 NI102626 NI102664 NI102474 NI102515 NI102558 NI102592 NI102627 NI102665 NI102475 NI102517 NI102559 NI102593 NI102628 NI102666 NI102667 NI102706 NI102742 NI102775 NI102810 NI102855 | | |
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NI103152

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