

BIOMEDICAL ENGINEERING – Device Exclusions List

This list contains items that are exempt from biomedical engineering analysis. If you are unsure whether a device meets the criteria to be exempt, please contact biomedical engineering.

Device	Conditions	Example
Previously inspected devices used in non-clinical areas	Researchers do not need to seek Biomedical Engineering approval for devices used in non-clinical areas that have a LMBME research device inspection label with an inspection date within the last year.	ECG machine with a LMBME research device label used in non-clinical area in ICORD that has an inspection date within the last year.
Devices used in private clinic	Researchers do not need to seek Biomedical Engineering approval for devices used in private clinics on VCH property	Vital signs monitor used in physician's private clinic in Diamond Healthcare Centre.
Devices used in homecare environment	Researchers do not need to seek Biomedical Engineering approval for devices used in homecare environment	Holter monitor used in homecare environment
VCH Owned Assets	Exempt if the intended use of the device in the study matches the intended use the device was designed for	Health authority owned vital signs monitor
Consumer Tablet/Smartphone	Exempt if the device is unmodified and has no patient applied parts	iPad
Activity monitors	Exempt unless used in a critical care or operating room environment	Fitbit