Blood Pressure Monitors:
Derivative Device Reviews

Terms and Conditions for Manufacturers

1. Introduction

This document aims to provide clear and consistent terms and conditions, for the review process of derivative blood pressure devices. These terms and conditions must be agreed and adhered to by all submitting parties.

The review process is to ensure efficiency and understanding of the steps required to carry out accurate, timely and unbiased reviews of BP devices with the outcomes being added to online lists for use by both HCPs and the public.

The NHS and NICE both recommend that devices purchased should be on the BIHS' approved list of devices.

2. Definition

A derivative device refers to a new-to market device which is an upgrade of an existing original device that has already:

- undergone a validation study - the study being completed,
- been published in a peer reviewed journal
- been approved by the BIHS.

Upgrades may, for example, constitute changes in branding, display, memory capacity or other non-crucial components of the device.

The BIHS will only assess derivatives of original devices which have successfully undergone a published validation study and have previously been added to the BIHS list of recommended devices.

A derivative device does not require a published validation study; therefore, recognition of new derivative devices relies on requests for assessment from the manufacturer or other body.

3. Process and Timelines

The BIHS aims to adhere to the following process and timelines:

- Review application requests can only be made through the BIHS online portal via the BIHS website by completing the form and submitting all required documentation which can be found at the following link: For Manufacturers | British & Irish Hypertension Society
- Start the submission through the online portal, completing the form and uploading all necessary documents and images.

- Make payment using the payment link, via credit card, or request an invoice which can take up to 7 working days to be sent and should be paid within 15days of receipt. The review will not commence until payment has been received.
- Once payment has been received, applications will be sent to reviewers within 3 days of receiving the payment.
- Reviewers will complete reviews of applications within 3 weeks allowing for any UK bank holidays.
- In the event any review is in contention, it will be, forwarded to the whole committee for a quorate decision.
- Manufacturers will be notified of a decision a maximum of 3 days after the end of the 5th week from the start of the review or before.
- The device will be added to the approved or not approved lists on the website within 5 days of informing the manufacturer
- If a decision has not been made within 5 weeks, the manufacturer will be informed and further information requested if required.
- Any information not completed or not supplied by the submitter in the first instance, will delay the 5-week timeline.

The BIHS will not be responsible for any delays caused by information/documents that have not been provided or any incomplete/incorrectly completed forms.

Reviews of applications cannot be cancelled or refunded once the payment has been made.

4. Required information

The online portal requests that the following documentation is uploaded for review:

- The original publication from the journal in PDF format and URL;
- Images of the cuffs from both the original and derivative device opened out showing back and front – side by side for comparison
- Images of all sides of the original and derivative device – side by side for comparison
- Images of any upgrades or changes to the device
- Device manual
- Other major or minor device change form (template provided)

The BIHS will contact the submitter once if the form has not been completed correctly or the requested documents/images have not been provided. Submitters will not be continually chased for information that has been requested in these terms and through the portal.

5. Fees

The fees for the purpose of reviewing derivative devices where an original device has been previously approved by the BIHS is £620+VAT.

The fees can be paid by way of a credit/debit card through a payment link which can be found on the portal at the start of your submission, or you can request an invoice from info@bihs.org.uk

An invoice can take up to 7 working days to be sent and should be paid within 15 working days of receipt. The review will not commence until payment has been received.

6. Caveats

Please ensure your application matches your device. Caveats will not be considered to avoid misleading the public and professionals.

Devices will either be 'Approved' or Not Approved'. The BIHS decision is final.

7. Protocols

BIHS will only accept derivative device applications where the original device validation was carried out under the AAMI/ESH/ISO Universal Standard protocol (ISO 81060-2:2018) with its subsequent amendments - Universal Standard Amendment 1 (ISO 81060-2:2018/Amd1:2020); Universal Standard Amendment 2 (ISO 81060-2:2018/Amd2:2024)

8. Benefits

As of 1 January 2026, once a device has been approved, the following benefits will be provided for approval of derivative devices:

- BIHS approved logo to add to device packaging, for advertising and website (protocol to be followed)
- certificate of approval
- Approved device added to the website list
- Benefits if exhibiting at the ASM
- Monthly Communication to members on newly approved devices
- Receive regular newsletters from the BIHS

BIHS is building a **dynamic, searchable tool** to replace the static spreadsheet to help users find devices by use case, population group, or clinical setting. This will support procurement, practice, and patient guidance alike. When the tool is launched, the following benefits will be provided:

- Latest approved devices will be at the top of the searchable tool
- Option to add an image of the device to the tool

Use of the approved logo that will be supplied on approval of your application will only be permitted when the guidelines are followed.

BIHS Logo Use Guidelines January 2026

As a manufacturer you are welcome to display the specific BIHS approved logo on your website, specific approved device listings online and specific approved device packaging to acknowledge your approved device and commitment to public health.

To protect the integrity of the BIHS brand and ensure consistency across all materials, please follow these simple guidelines.

✅ DO

- Use the BIHS Approved logo only to acknowledge the approved device.

- Include the accompanying wording when using the logo:
  [Device make and model] has been reviewed and approved by the British and Irish Hypertension Society (BIHS) which can be found on the BIHS approved devices list (bihs.org.uk).
- Use the official logo file provided by BIHS (high-resolution PNG, JPG, or vector).
- Ensure the logo is clear, legible, and displayed on a neutral background.
- Maintain the logo's original proportions (no stretching, cropping, or colour changes).
- When linking online, link the logo to: www.bihs.org.uk

❌ **DO NOT**

- Alter or recreate the BIHS logo in any way (e.g. colours, fonts, shapes, or layout).
- Place the logo over busy or low-contrast backgrounds.
- Use the logo in proximity to specific products, packaging, or advertisements that could imply BIHS endorsement.
- Use the logo without the approved statement.
- Use the logo or BIHS name in paid advertising, sponsored content, or product promotion.
- Do not lift any logos from our site or communications
- Use the logo in any way that could misrepresent the relationship between your organisation and BIHS.

Approval and Support

If there are any doubts in whether the intended use meets these guidelines, please contact info@bihs.org.uk before publication.

The BIHS is happy to provide support or visual checks to ensure your materials align with BIHS brand standards.

If these terms are not followed, use of the logo is abused, passed to other companies or individuals, used on unapproved devices or without specific permissions, the BIHS will ask that the logo is removed, rights to use the logo will be revoked, it will be noted that the manufacturer is a risk to the BIHS, further devices may not be reviewed and the BIHS may take further legal steps.

Notes

If a derivative device has been approved in years prior to 2026, the benefits will not have been received. In order to avail from these benefits, please contact the team on info@bihs.org.uk so that the relevant checks can be made and the specific approved logo sent for use.

If an original device has been approved in years prior to 2026, benefits will not have been received. In order to avail from these benefits, please contact the team on info@bihs.org.uk so that the relevant checks can be made and the specific approved logo sent for use.

Please **DO NOT** assume the benefits if the device is approved.

A specific logo has been designed for the purpose of approved devices. **The BIHS main logo should NOT be used in any way.**

If there any queries, please contact info@bihs.org.uk