

Housing for an implantable medical device

The present invention relates to a housing for an implantable medical device (IMD).

5 Housings for IMDs house the most important device components and protect them from the environment at the implantation site. The device housings may have external interfaces, e.g. for connecting device components electrically and mechanically (for example, for stimulation electrodes for cardiac pacemaker implants), or may have sensor interfaces for measuring body parameters.

10

There are IMDs whose device housings are implanted in a skin or tissue pocket of the patient (for example, for cardiac pacemaker implants or spinal cord stimulators). The device housings should be dimensioned as small as possible and should be shaped such that they do not cause discomfort to the patient. Known from the prior art are flat, rounded housing
15 shapes that cause a slight bulge in the skin that projects outward as little as possible.

20

As a rule, cardiac pacemakers, implantable cardioverter-defibrillators (ICD), and CRT (cardiac resynchronization therapy) devices have a flat, rounded housing made of metal. The housing is mechanically connected to a header component (hereinafter referred to as a
20 header) that typically comprises cast epoxy resin and provides the connectors for the electrode leads. Electrical lines lead out of the device housing into the header to the connectors for the electrode leads and in this way provide the electrical connection between electrodes and the components arranged in the interior of the housing, such as the device processor, battery, or, in the case of ICDs, the shock capacitor. The device housing with
25 header is implanted in the upper chest region, above the ribs, below the clavicle, in a skin or tissue pocket. The device housing connected to the header is called the housing arrangement in the following.

30

Cardiac pacemakers, ICDs, and CRT devices are known in the prior art in which the housing arrangement, made of device housing and header, is embodied flat and has a circular outer contour. One problem with such housing arrangements is that they can easily rotate in the

skin or tissue pocket. The electrode leads connected to the header turn at the same time, which can result in the electrode breaking.

Also known are housing arrangements in which the device housing is wider than it is high,
5 or is higher than it is wide. One drawback of such housing arrangements is that the device housing tends to “wobble” on the ribs of the patient. The wobbling is caused by the space between the ribs of the patient and the device housing, this space being relatively large for such housing arrangements, since the device housing has a relatively long flat side that does not follow the contour of the ribs. The “wobbling” is pronounced and uncomfortable, in
10 particular in patients having a small ribcage, the rib contours of which have a smaller circular radius.

During implantation of such housing arrangements, a comparatively small incision is made into the patient’s skin, and this is associated with the drawback that the doctor has a limited
15 amount of space for fashioning the skin or tissue pocket.

Aspects of the invention are defined in the independent claims. Advantageous exemplary embodiments of the invention are found in the dependent claims.

20 Thus it may be possible to provide a device housing for an IMD that is comfortable for the patient to have under his skin, i.e., it is pain-free and essentially has no perceptible tensile or tugging forces. It may also be possible to provide a device housing for an IMD that “wobbles” as little as possible when it is implanted above the ribs of the patient.

25 It may also be possible to provide a device housing for an IMD that does not easily rotate when implanted.

It may also be possible to provide a device housing for an IMD that may be implanted in a simple, rapid, and controlled manner.

30

According to one arrangement, a device housing for an IMD is suggested, the device housing having:

- a front side,
- a flat end face that is arranged perpendicular to the front side and connects to a straight upper edge of the front side,
- the front side having a maximum width (B_{max}) that is measured parallel to the straight upper edge, and a maximum height (H_{max}) that is measured perpendicular to the straight edge,

characterized in that the ratio R of maximum width (B_{max}) to maximum height (H_{max}), i.e. B_{max}/H_{max} , is between 1.05 and 1.35.

In this manner, the suggested device housing has optimal geometry to be comfortable for the patient when in use, i.e., the “wobbling” on the ribs is prevented or sharply reduced, since the device housing does not have a long surface. At the same time, rotation in the skin or tissue pocket is prevented because the housing is not circular.

According to one advantageous exemplary embodiment, the ratio R , i.e. B_{max}/H_{max} , is between 1.1 and 1.30, or is between 1.15 and 1.275, or is between 1.2 and 1.275; or is 1.25.

Moreover, the front side may have a maximum width (B_{max}) of 40 mm to 70 mm, or of 50 mm to 65 mm, or of 55 mm to 65 mm, or of 60 mm.

The front side may have a maximum height (H_{max}) of 40 mm to 70 mm, or of 40 mm to 60 mm, or of 45 mm to 55 mm, or of 45 mm to 52 mm, or of 48 mm.

The aforesaid dimensions for ratio R , B_{max} , and H_{max} have proven to be particularly effective for attaining the aforesaid objects.

The device housing may have a maximum thickness D_{max} , the thickness being measured perpendicular to the plane of the front side, and the maximum thickness being from 9 mm to 15 mm, or from 9 mm to 12 mm, or from 10 mm to 11 mm, or being 10 mm.

The aforesaid thicknesses permit an ergonomic, thin device housing, with sufficient interior volume for housing the device components, if other geometries according to the suggestion are selected for the device housing in combination.

5 The device housing may have a back side that is arranged congruent with and opposing the front side, and wherein the flat end face connects to a straight upper edge of the back side. The device housing may also comprise two housing shells, the first housing shell having the front side and the second housing shell having the back side, the first and second housing shells being embodied symmetrically.

10 .

In this way it is possible for the device housing to have a symmetrical structure. A symmetrical structure is advantageous for patients that have an IMD implanted on the right side, instead of on the left side. Thus the IMD with the device housing is simply turned around and may be implanted in a mirror-image, so that it has the same properties in terms
15 of comfort for the patient as for a typical patient with the IMD implanted on the left side.

The outer contour of the front side of the device housing may have curves with at least two different curve radii. A maximum curve radius of 12 cm, or 11 cm, or 10 cm, or 9.5 cm is not exceeded.

20

The selection of the curve radii ensures that the implant does not have any long surfaces, so that “wobbling” on the ribs is prevented.

The ratio of the surface area of the front side to the surface area of a rectangle that spans the
25 maximum width (B_{max}) and maximum height (H_{max}) of the front side, i.e., $\frac{\text{surface area (front side)}}{\text{surface area (back side)}}$, may be at least 0.6, or at least 0.7, or at least 0.75, or at least 0.8, or at least 0.85, or at least 0.9, or at least 0.95.

Moreover, the ratio of the surface area of the front side to the surface area of an ellipse that
30 spans maximum width (B_{max}) and maximum height (H_{max}) of the front side, i.e.,

$\frac{\text{surface area (front side)}}{\text{surface area (ellipse)}}$, may be at most 1.5, or at most 1.4, or at most 1.3, or at most 1.2, or at most 1.15, or at most 1.1.

Selecting the “fill factor” according to the suggestion ensures that, for one thing, the shape of the device housing is “somewhat circular” or at least “somewhat elliptical” so that sharp corners in the contour and long surfaces are prevented in order to increase comfort and to prevent “wobbling.”

The device housing may have rounded edges. These may increase wearing comfort for the patient.

In addition, a housing arrangement for an IMD is suggested that comprises a device housing and a header (3). The header is connected to the device housing at the flat end face of the device housing.

The IMD may be a cardiac pacemaker, an implantable cardioverter defibrillator, or a CRT device.

In addition, a method for implanting a housing arrangement is suggested. The method comprises the steps:

- Opening the body tissue of a patient below the clavicle by means of an incision,
- Preparing a tissue pocket that approximately corresponds in size to the volume of the housing arrangement,
- Inserting the device housing into the tissue pocket,
- Closing the tissue pocket.

The length of the incision is less than or equal to the maximum width (Bmax) of the front side of the device housing. Alternatively, the length of the incision may be less than or equal to the maximum height (Hmax) of the front side plus the height of the header. In this way the incision made has the optimum length for preparing a skin or tissue pocket.

Additional advantageous embodiments may be found in the figures and descriptions of the figures. The figures illustrate different exemplary aspects of the invention and should not be considered as limiting for the protected subject matter.

5

Brief description of the figures

Figure 1 is a schematic view of a housing arrangement;

10 Figure 2 is a schematic side view of a housing arrangement;

Figure 3 is a schematic representation of how the curve radius for the contour of the device housing is determined;

15 Figure 4 is a schematic representation of how a fill factor for the surface area of the front side of the device housing is determined;

Figure 5 is a schematic representation of how a fill factor for the surface area of the front side of the device housing is determined.

20

Detailed description of the figures

Figure 1 illustrates the contours of a housing arrangement 1, comprising device housing 2
25 and header 3. The device housing 2 has a front side 4 and a flat end face 6 that is arranged perpendicular to the front side 4 and connects to a straight upper edge 5 of the front side. The front side 4 has a maximum width B_{max} that is measured parallel to the straight upper edge 5. The front side 4 also has a maximum height H_{max} that is measured perpendicular to the straight upper edge 5. The outer contour of the front side 4 comprises curves having at
30 least two different curve radii r_1, r_2, r_3 .

Figure 2 is a schematic side view of the housing arrangement. The maximum thickness D_{max} of the device housing, which is measured perpendicular to the front side 4, may be seen. The device housing 2 also has a back side 4' that may be configured congruent with the front side 4.

5

Figure 3 schematically illustrates a measurement of the curve radius 7'. The corresponding circle segment is shown with a broken line. A circle with a corresponding circle segment is overlaid and the circle radius 81 corresponds to the curve radius 7'.

10 Figure 4 schematically illustrates how the fill factor, which is found using the ratio of the surface area of the front side 4 to a rectangle 9 that spans B_{max} and H_{max} , is determined. The shaded area corresponds to the portion of the rectangular surface area that is not filled by the surface area of the front side 4.

15 Figure 5 schematically depicts how the fill factor that is found using the ratio of the surface area of the front side 4 to an ellipse 10 that has B_{max} and H_{max} as principle axis and secondary axis is determined. The area of the front side 4 not covered by the shaded surface area corresponds to the portion of the surface area that projects beyond the ellipse.

20

Patent claims

1. A device housing (2) for an IMD comprising:

- a front side (4),
- a flat end face (6) that is arranged perpendicular to the front side (4) and connects to a straight upper edge (5) of the front side,
- the front side (4) having a maximum width (Bmax) that is measured parallel to the straight upper edge (5), and a maximum height (Hmax) that is measured perpendicular to the straight upper edge (5),

characterized in that the ratio R of maximum width (Bmax) to maximum height (Hmax), i.e. $B_{\max}/H_{\max}$, is between 1.05 and 1.35,

wherein the ratio of the surface area of the front side (4) to the surface area of a rectangle (9) that spans the maximum width (Bmax) and maximum height (Hmax),

i.e. $\frac{\text{surface area (front side)}}{\text{surface area (rectangle)}}$, is at least 0.6, or at least 0.7, or at least 0.75, or at least 0.8,

or at least 0.85, or at least 0.9, or at least 0.95.

2. The device housing (2) according to claim 1, wherein R is between 1.1 and 1.30, or between 1.15 and 1.275, or between 1.2 and 1.275, or is 1.25.

3. The device housing (2) according to claim 1 or 2, wherein the maximum width (Bmax) is from 40 mm to 70 mm, or from 50 mm to 65 mm, or from 55 mm to 65 mm, or is 60 mm.

4. The device housing (2) according to any of the preceding claims, wherein the maximum height (Hmax) is from 40 mm to 70 mm, or from 40 mm to 60 mm, or from 45 mm to 55 mm, or from 45 mm to 52 mm, or is 48 mm.

5. The device housing (2) according to any of the preceding claims, wherein the device housing (2) has a maximum thickness (Dmax), the thickness being measured perpendicular to the plane of the front side, and the maximum thickness being from 9 mm to 15 mm, or from 9 mm to 12 mm, or from 10 mm to 11 mm, or being 10 mm.

6. The device housing (2) according to any of the preceding claims, wherein the device housing (2) has a back side (4') that is arranged congruent with and opposing the front side (4), and wherein the flat end face (6) connects to a straight upper edge of the back side (4').
7. The device housing (2) according to any of the preceding claims, wherein the outer contour of the front side (4) has curves with at least two different curve radii (7, 7', 7''), wherein a maximum curve radius (8) of 12 cm, or 11 cm, or 10 cm, or 9.5 is not exceeded.
8. The device housing (2) according to any of the preceding claims, wherein the ratio of the surface area of the front side (4) to the surface area of an ellipse (10) that spans maximum width (Bmax) and maximum height (Hmax), i.e. $\frac{\text{surface area (front side)}}{\text{surface area (ellipse)}}$, is at most 1.5, or at most 1.4, or at most 1.3, or at most 1.2, or at most 1.15, or at most 1.1.
9. The device housing (2) according to any of the preceding claims, the device housing (2) comprising two housing shells, the first housing shell having the front side (4) and the second housing shell having the back side (4'), the first and second housing shells being embodied symmetrically.
10. The device housing (2) according to any of the preceding claims, the device housing (2) having rounded edges.
11. A housing arrangement (1) for an IMD, comprising a device housing (2) according to any of the preceding claims and a header (3), wherein the header (3) is connected to the device housing (2) at the flat end face (6).

12. A device housing (2) or a housing arrangement (1) according to any of the preceding claims, wherein the IMD is a cardiac pacemaker, an implantable cardioverter-defibrillator, or a CRT device.
- 5 13. A method for implanting a housing arrangement (1) according to claim 11 or 12, comprising the steps:
- Opening the tissue of a patient below the clavicle by means of an incision,
 - Preparing a tissue pocket that approximately corresponds in size to the volume of the housing arrangement (1),
 - 10 – Inserting the device housing (1) into the tissue pocket,
 - Closing the tissue pocket.
14. The method according to claim 13, the maximum length of the incision being less than or equal to the maximum width (Bmax) of the front side (4) of the device housing (2), or the being less than or equal to the maximum height (Hmax) of the front side (4) of the device housing (2) plus the height of the header (3).
- 15