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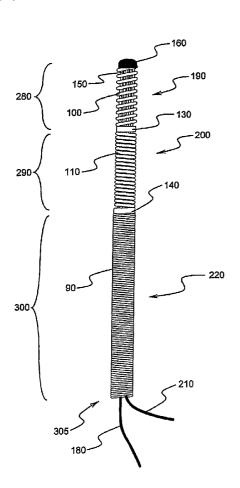
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(54) Title: IMPLANTABLE BIOSENSOR SYSTEM, APPARATUS AND METHOD



(57) Abstract: An implantable biosensor assembly and system includes an enzymatic sensor probe from which subcutaneous and interstitial glucose levels may be inferred. The assembly may be associated by direct percutaneous convection with electronics, such as for signal amplification, sensor polarization, and data download, manipulation, display, and storage. The biosensor comprises a miniature probe characterized by lateral flexibility and tensile strength and has large electrode surface area for increased sensitivity. Irritation of tissues surrounding the probe is minimized due to ease of flexibility and small cross section of the sensor. Foreign body reaction is diminished due to a microscopically rough porous probe surface.

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C. DOCU	JMENTS CONSIDERED TO BE RELEVANT			
Category *	Citation of document, with indication, where app		Relevant to claim No.	
X	US 4,703,756 A (GOUGH et al.) 03 November 1987		1, 15, and 16	
 Y	lines 1-22; col. 5, lines 3-21; col. 6, lie 13-col. 7, line	e30	1-6, 7, 12, 13, 15, 16, 18, 23, 24, 26, 50, 53	
A			8-11,14,17,19-22, 25,27-45,51,52,54-57	
X	US 6,360,888 B1 (MCIVOR et al.) 26 March 2002 (2	26.03.2002), figs. 2, 6, 7, and 13-15;	46, 47	
 A	col. 10, line 30-col. 12, line 15.		8-11,14,17,19-22, 25,27-45,51,52,54-57	
Y 	US 5,165,407 A (WILSON et al.) 24 November 1992 43; col. 3, lines 38-42; col. 4, line 64-col. 5, line 38;		1, 7, 12, 13, 15, 16, 18, 23, 26, 50, 53	
A	19.		8-11,14,17,19-22, 25,27-45,51,52,54-57	
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priority d	nent published prior to the international filing date but later than the "&" document member of the same patent family y date claimed			
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C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT				
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
Y, P	US 6,613,379 B2 (WARD et al.) 02 September 2003 (02.09.2003), col. 3, lines 44-55.	23, 24		
A, P		8-11,14,17,19-22, 25,27-45,51,52,54-57		
Y	US 5,527,444 A (SWEENEY, JR.) 18 June 1996 (18.06.1996), fig.2; col. 1, lines 31-35;	2-6 and 12		
A	col. 3, lines 14-18; col. 5, line 48-col. 6, line 67.	8-11,14,17,19-22, 25,27-45,51,52,54-57		
A	US 4,561,963 A (OWEN et al.) 31 December 1985 (31.12.1985), entire document.	8-11,14,17,19-22, 25,27-45,51,52,54-57		
A	US 4,861,454 A (USHIZAWA et al.) 29 August 1989 (29.08.1989), enitre document.	8-11,14,17,19-22, 25,27-45,51,52,54-57		
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