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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
G01B 7/004, G01D 5/20, A61M 25/095, A61B 5/06

A1

(11) International Publication Number: **WO 00/68637**

(43) International Publication Date: 16 November 2000 (16.11.00)

(21) International Application Number: PCT/GB00/01429

(22) International Filing Date: 25 April 2000 (25.04.00)

(30) Priority Data:

9909332.0	23 April 1999 (23.04.99)	GB
9919979.6	24 August 1999 (24.08.99)	GB
9919978.8	24 August 1999 (24.08.99)	GB

(71) Applicant *(for all designated States except US)*: SENTEC LIMITED [GB/GB]; Terrington House, 13–15 Hills Road, Cambridge, Cambridgeshire CB2 1GE (GB).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: DAMES, Andrew [GB/GB]; 74 deFreville Ave, Cambridge, Cambridgeshire CB4 1HU (GB). COLBY, Edward, Grellier [GB/GB]; 45 Argyl Road, Cambridge, Cambridgeshire CB1 3LR (GB). ENGLAND, James, Mark, Carson [GB/GB]; 44A Butt Lane, Milton, Cambridge, Cambridgeshire CB4 6DG (GB).

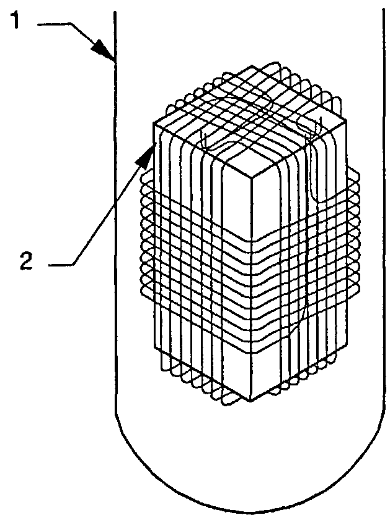
(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: CATHETER DEVICE

(57) Abstract

A catheter incorporating magnetic field detection means is described wherein the position and orientation of the catheter tip may be determined and used in minimally–invasive surgery.



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Catheter Device

Field of the Invention

This invention relates to the field of position measurement applied to location of a small object, specifically an object or objects mounted into a catheter tip. The invention described is a catheter incorporating miniature magnetic field detection devices.

Background

Inductive position location has been described in many patent applications. The technology relies on AC electromagnetic sensing technology. In these implementations there are three orthogonal transmit coils mounted on a fixed object and three receive coils mounted on the moveable object. Position is sensed by measuring the nine coupling coefficients between these coil sets, and making use of knowledge of the spatial variation of dipole fields from these coils. Patents US4054881, US314251, US4298874, US03660648, US03868565, US03983474 and US04017858 describe the prior art.

Alternate methods of detecting the catheter position have been demonstrated in the prior-art. X-ray location is commonly used as the surgeon is familiar with the image data format produced. However, with this method the patient is exposed to potentially harmful ionising radiation. Alternatively, ultrasound images may be used. Ultrasound measurement systems determine distance from a propagation time measurement. This will be inaccurate due to differences in the sound velocity in various body tissues.

Inductive measurement systems are inherently not affected by human tissue as this is mostly composed of non-conductive, non-ferromagnetic material. Therefore placing the patient into the interrogation volume will not cause position measurement errors.

The invention requires a miniature '3 orthogonal axis' coil to be incorporated within the catheter tip. The construction techniques describes allows a suitably compact air-cored or ferrite-cored coil configuration. Further the use of a miniature coil assembly generates extremely low level signals and these are transported to the processing electronics with minimal interference from the reference magnetic field. This is achieved by the construction of a specialised lead incorporated into the catheter.

Summary of the Invention

According to the present invention, an apparatus for detecting the position and pointing angle of a catheter tip is described wherein a miniature, 3-axis orthogonal coil set is incorporated into the catheter tip.

A specialised cable is incorporated to transport the voltage induced in the receiver coil set by the reference magnetic field with minimal susceptibility to inductive or capacitive interference.

Brief Description of the Drawings

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 illustrates the construction of the catheter,
Figure 2 shows the coil assembly,
Figure 3 illustrates the system for generating output signals from the catheter and converting these into position and orientation information.

Detailed Description

The catheter tip, 1, has a small coil assembly, 2 placed within the inside of a 10 french catheter. The coil assembly, 2, is wound onto a block of plastic, 3, with dimensions 4mm long and 2mm square section. Around the block, 3, there are three orthogonal coils of wire, 4, 5 and 6 wound as shown in Figure 2. The coils are 40 turns of 50μm enamelled copper wire tight wound as single layer coil and with the connections brought together.

The catheter, 7, has the coil assembly placed at the tip, 8. The coil assembly is connected to the end of the catheter by fine 50um copper wire. The cable consists of three twisted pairs, with each twisted pair constructed from two 50um wire with 25 twists per cm. The three twisted pairs are loosely twisted with 3 twists per cm.

The length of the twisted cable must be kept relatively short, to avoid unwanted coupling between the cable and the transmit coil assembly, 10, which could distort the signals intentionally coupled into the coil assembly at the catheter tip, 8. Two methods may be used to achieve this.

In the first method, a step-up toroidal transformer, mounted in a small, magnetically shielded enclosure, is used to increase the signal levels relative to the unintended coupling. A suitable transformer is based on a Philips TN14/9/5-3E25 core, wound with 100 μm wire with a turns ratio of 15:60. For optimum performance, this is achieved using 15 turns of twisted 5-strand wire. Four strands are connected in series to form 60 turns of secondary, and the fifth strand forms the primary.

The second method is to use a low-noise in-line preamplifier, again mounted in a magnetically screened enclosure. This second method is particularly advantageous when long cable lengths are required between the catheter, 7, and the signal processing, 11.

The coil assembly within the catheter tip, 8, is placed within the vector fields, 9, generated by one or more transmit coil assemblies, 10. Each transmitter coil assembly, 10, comprises three orthogonal coils of wire, and generates three dipole AC magnetic field patterns at different frequencies, for example 10, 11 and 12kHz. The processing electronics, 11, generates the required drive signals for the transmitter antenna and provides the receive signal processing. . In the preferred embodiment, the drive amplifiers for the coils are current-mode, and the coils are series-resonated for efficiency and harmonic purity. The signal processing calculates the position and orientation (6 degrees of freedom) defining the catheter tip position relative to the transmitter antenna.

The processing used is known in the art and below is a brief summary. Each transmitter coil generates a field pattern with a near-dipole distribution in the far field. Each transmitter coil runs at a different frequency. In the preferred embodiment, all the transmitters are derived from a common clock signal, such that for certain time period (e.g. 1 ms) , an integral number of cycles of each transmitter can be counted. This is advantageous for synchronous demodulation. The three receiver coils, 2, together measure the field vector (i.e. amplitude and direction) at the catheter tip of each of the transmitted frequencies. A phase-sensitive method of demodulation is used in the preferred embodiment, using the detection phase determined as part of the transmit-receive calibration process. For each orthogonal transmitter set there are nine measured coupling co-efficients (a 3x3 coupling matrix) and these are processed using the known field patterns from a magnetic dipole, and measured field values where required, to calculate the best estimate of the catheter position and orientation.

Calibration coefficients are incorporated into the processing to correct for imperfections in the transmit and receive coils, and field distortions caused by either fixed position ferromagnetic or conductive materials placed within the operating volume. The calibration of the catheter and the calibration of the transmitter coil and operating environment are carried out separately. The catheter calibration records the sensitivity and orthogonality of the catheter coils at the operating frequencies. This is achieved independently of the transmitter using a calibrated uniform field generator.

The transmit field is mapped using a specialised test jig that allows translation of a calibrated receive coil assembly within the operating volume. The jig records the known physical position of the receive coil assembly. The magnetic fields are characterised over the interrogation volume at a number of different points, and these values are placed in a calibration database in the processing unit, 11.

Receiver Non-orthogonality and Gain Error

The three coils, 4, 5, 6, in the catheter are substantially orthogonal. The "orthogonality matrix" for the three axis receiver coil is a 3x3 matrix, **R**, whose columns represent the field coupling from three unit orthogonal dipoles. A uniform field may be generated by a set of Helmholtz coils to determine the calibration matrix **R**, using the method described below.

The coil assembly, 2, is placed at the centre of a three-axis Helmholtz (or similar) coil set, driven at the standard transmit drive frequencies used for the transmitter coil set. A jig is used to constrain the possible orientations of the coil assembly, 2, to be orthogonal to each other, and (nominally) aligned with the Helmholtz coil set axes.

A series of measurements are taken of the 3x3 coupling matrix between the transmit and receive coils in four different, orthogonal orientations – one nominally a ligned, and three in which a 90º rotation has been applied. In each case, there will be three nominal terms in which the coupling is large, and six near-zero terms. In each case, for the three largest coefficients, the ratio between the nominal coupling (+/-1) and the actual coupling is measured, together with the correct detection phase. This allows for the correction of different drive levels and drive phases between the three driven coils – i.e. it allows calibration of the Helmholtz coils themselves.

With the two coils nominally aligned, the coupling matrix, corrected for different transmitter drive levels, should ideally be diagonal with all elements equal. In practice, it will be neither diagonal, nor will it have equal magnitude elements, and is referred to as the orthogonality matrix, $\mathbf{R}$, of the receiver coil set.

Each catheter will have a unique orthogonality matrix, $\mathbf{R}$. This ensures consistent measurements when using different catheters. The calibration data may be stored on a data device associated with the catheter. If this forms part of the catheter itself, it may be stored in an electronic memory chip incorporated into the catheter or its connector, and read by the processing box, 11. The data may alternatively be part of the catheter packaging, in the form of a smart card, bar code, EPROM or floppy disc, which can again be read by the processing box, 11.

Non-orthogonality and receiver gain errors are corrected in the measurement system by multiplying the measured 3x3 transmit / receive coupling matrix by the inverse of the measured calibration orthogonality/gain matrix, $\mathbf{R}$.

Transmitter non-Uniformity

Metallic objects fixed in the frame of reference of the transmit coil set cause significant field distortions. These may be, for example, caused by metal sheets surrounding equipment, the patient support etc. They may be quite severe, to the extent that a conventional "solve" for position assuming ideal dipoles will fail altogether. Therefore, a method is required which is able to cope well with both moderate and severe distortions.

In all the distortion corrections described below, the first step is to measure the field vectors over an array of points within the measurement volume – i.e. a calibration. This is ideally achieved using a calibrated three-axis receiver coil of known orthogonality, whose position and orientation (in the frame of reference of the transmitter coil set) is measured using a suitable co-ordinate measurement apparatus. This measurement should include the phase of the AC field vector, as the phase of the fields may vary in the presence of eddy-currents in metal objects.

These measurements generate an array of field vectors over 3D space. For each point, there will be a field vector corresponding to each transmit coil. Around 1000 points are sufficient in cases where distortion is moderate. More points may be used closer to regions where more distortions are discovered – i.e. an "adaptive" mesh size for the points, provided an appropriate data structure is used to store and manipulate this data.

To minimise the number of points required for distortion correction, and thereby minimise the errors introduced by the interpolation process it is beneficial to construct an interpolation system that gives a small interpolation error if the field patterns from the transmitters are perfect dipoles. In this way, the interpolation calculates only deviations from the ideal dipole radiation pattern, rather than the complete set of field values. Whilst it is not possible to achieve this perfectly, a significant improvement over the $\frac{1}{r^3}$ behaviour can be made by using one of the methods shown below.

Method 1

For a 3-axis transit and 3-axis receive coil set, the raw measurement data consists of a 3x3 matrix of coupling coefficients, **Y**, between the receiver coils and the transmitter coils. This is corrected for receiver orthogonality and gain errors as described above using the equation

$$\mathbf{Y}' = \mathbf{R}^{-1}\mathbf{Y}$$

The rows of **Y'** are the couplings into the *x*, *y* and *z* receiver coils, whilst the columns represent the three transmit coil vectors in the receiver frame of reference. Therefore, the three transmit field amplitudes at the receiver (A_x, A_y and A_z) may be obtained simply from magnitudes of the three column vectors of **Y'**, and the three angles between the fields (θ_x, θ_y and θ_z) can be obtained from the dot products of the columns. These six values are the basic numbers which are used to resolve the position of the receiver coil. A seventh useful number is

$$r = \sqrt{(A_x^{\ 2} + A_y^{\ 2} + A_z^{\ 2})}$$

which, for an ideal dipole source, is proportional to the cube of the distance from the transmitter.

Data from the coil calibration measurements may not line on a regular Cartesian grid. A favourable method to store the data is as a cross-linked "tree" structure, in which each point stores references to the locations of a number of nearest neighbours (in physical space), which may or may not be uniformly spaced.

The data stored from the calibration at each point consists of the following ten data items, $D_0..D_9$:

$$\begin{aligned}
D_0 &= \theta_x - \tfrac{\pi}{2} \\
D_1 &= \theta_y - \tfrac{\pi}{2} \\
D_2 &= \theta_z - \tfrac{\pi}{2} \\
D_3 &= \frac{A_x}{A_y} \\
D_4 &= \frac{A_x}{A_z} \\
D_5 &= \frac{A_y}{A_z} \\
D_6 &= \ln(r) \\
D_7 &= x \\
D_8 &= y \\
D_9 &= z
\end{aligned}$$

The principle of the distortion correction process is to convert the (A_x, A_y and A_z) and (θ_x, θ_y and θ_z) into an equivalent seat of measured items, $M_0..M_9$. An error function is defined which is the sum of the squares of the differences between the seven measured terms and the seven stored calibration terms:

$$Err = \sum_{i=0}^{6} w_i \left[D_i - M_i\right]^2$$

where w_i is a weighting factor (which may optionally depend on the position). Initially, a search algorithm is used which determines the nearest calibration point to the unknown measurement. A number of alternative methods may then be applied, depending on the degree of the field distortions, the number of calibration points and the accuracy required.

In one embodiment, a multi-variate non-linear numerical minimisation algorithm (such as Powell's method) is used to determine the point (x,y,z) close to this nearest calibration point where the error in minimum. This search can be constrained to the surface of a sphere by the seventh term, $h(r)$. Interpolation (such as quadratic interpolation) is used to determine values of the seven data items in between the measured data points, such that the error function may be calculated at arbitrary points in space. The outcome of this process is an estimated (x,y,z) position.

Once the position is known, the orientation is calculated by back-substitution: the interpolated values of $D_0..D_6$ are used to calculate the field vectors at the point of interest. A numerical method is used to calculate the rotation matrix required to operate on this set of field vectors to give the closest match to the (corrected) measured matrix $\mathbf{Y'}$.

Method 2

An alternative method involves storing the local transmitter non-orthogonality matrix, $\mathbf{X}$, at discrete, known calibration points, using a previously calibrated receiver coil assembly (with orthogonality matrix $\mathbf{R}$). During calibration, the expected coupling matrix, $\mathbf{Y}_e$, can be calculated from the known position and orientation of the receiver coil assembly with respect to the transmitter coil assembly. The measured coupling, $\mathbf{Y}$, and the expected coupling, $\mathbf{Y}_e$, are related by the equation:

$$\mathbf{Y}_e = \mathbf{R}^{-1}\mathbf{Y}\mathbf{X}^{-1}$$

Hence

$$\mathbf{X} = \mathbf{Y}_e^{-1}\mathbf{R}^{-1}\mathbf{Y}$$

The measured coupling matrix near this calibration point may then be corrected for orthogonality using the equation:

$$\mathbf{Y}'' = \mathbf{R}^{-1}\mathbf{Y}\mathbf{X}^{-1}$$

The coupling matrix, $\mathbf{Y}''$, corresponds to a near-ideal situation involving perfect dipoles. A number of standard solution methods to the problem may then be used to determine both the orientation and to calculate the position.

Of course, there is no *a priori* knowledge of the position, and therefore which is the most appropriate orthogonality correction matrix to use. One solution is to use an iterative method to correct for the position. As described above, the nearest calibration data set for the coupling matrix, uncorrected for transmitter orthogonality, $\mathbf{Y}'=\mathbf{RY}$, is first determined. The transmit orthogonality matrix, $\mathbf{X}$, from this point is then used to correct the measured data, and the resulting matrix is used to calculate the first estimate of position. An iterative process can then be applied as follows: the position estimate is used to obtain an interpolated orthogonality matrix at this position. This is applied to the coupling matrix $\mathbf{Y}'$, and this is used to re-calculate the position. This process is repeated until the solution converges to an acceptable accuracy.

This calibration data is related to the installed configuration and is an installation process. The data is stored within the processing system, 11.

Further Embodiments

In the basic system described above there are three transmit coils and three receive coils. This arrangement leads to a measurement volume which is fundamentally spherical, centred on the transmit coil set. In practical applications, catheters must be tracked within the human body, which is a far from spherical volume. In further embodiments of the system, additional transmit coils sets are placed in such a way as to cover the interrogation volume more uniformly. For example, these might be incorporated into various points on the patient support structure, to generate an elongated interrogation volume. Frequency multiplexing is utilised to distinguish the multiple dipole magnetic dipole fields in the operating volume – i.e. each coil transmits at a different frequency. The receive coil assembly in the catheter tip measures all the field vectors and can again estimate the catheter position and orientation using an error minimisation algorithm. An additional benefit of this configuration is that distortions to the magnetic field caused by moveable conducting or ferrous material can be better accommodated. The increased number of measurands allow for the field effects of the unknown moveable object to be better approximated.

In a further embodiment the receiver coil assembly is a single coil. A minimum of six transmit coils are required for this measurement, typically as two sets of three orthogonal coils in different locations. It is not possible to resolve orientations about the axis of the catheter using this configuration, but the coil can be made more compact. Frequency multiplexing is again used to generate the magnetic dipole field patterns in the operating volume. Further combinations of transmit and receive coil configurations randomly spaced and orientated around the operating volume are possible, provided they provide sufficient measurands to provide a unique soluble position and orientation.

In a further embodiment there are provided two or more receive coil assemblies spaced apart within the catheter. These allow for the path of the catheter to be measured. This can be extended to multiple instances of receive coil assemblies within the catheter that will allow the complete catheter 'path' to be measured, interpolating the path between points using a spline fit.

A further embodiment of the catheter device is where the coil assembly is fitted to a semi-rigid member that can move within the catheter tube. The coil assembly may be moved along the inside of the catheter, and this allows the path of the catheter to be determined.

The receiver coil may be used as a transmitter and visa-versa.

Improved signal levels can be obtained by using ferrite cores in any of the coils.

Claims

1) A catheter device incorporating magnetic field sensing means used in a catheter location apparatus involving the following steps:

   a) generation of a set of three or more independent magnetic vector fields which are either time, frequency or phase-multiplexed, and arranged such that, at any point in the interrogation volume, the field vectors have a unique (to within a mirror-plane ambiguity) combination of relative orientation and absolute magnitude which defines the co-ordinates of the point

   b) measurement of the magnitudes and orientations of the magnetic field vectors in the frame of reference of the catheter, by a catheter magnetic sensing means

   c) processing of the measured field values to calculate position using a calibration routine with field values that have been pre-measured.

2) A device according to claim 1, where the magnetic detection means is by a coil of wire and a.c. magnetic fields are used.

3) A device according to claim 1 and 2, incorporating a twisted pair lead and screening mechanism in the catheter.

4) A device according to claim 1, 2 and 3, where the magnetic detection means is by three coils with substantially orthogonal magnetic axes.

5) A device according to any of the preceding claims, wherein the processing demodulates the received induced AC voltage at the correct phase to reduce the effect of ferromagnetic materials in the detection volume.

6) A device according to any of the preceding claims incorporating a correction method incorporating steps of:

a) Calibration of the vector field patterns at known locations

b) Estimation of position using measurement and calibration data that gives the best fit against the set of measurands

7) A device according to any of the preceding claims 4 incorporating calibration data to calibrate for the coil manufacturing errors.

8) A device according to any of the preceding claims incorporating an electronic amplifier in the lead of the catheter

FIGURES

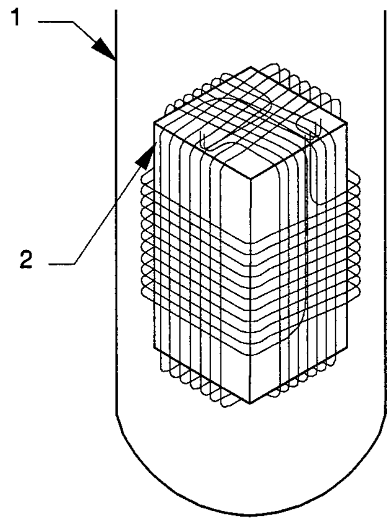

Figure 1

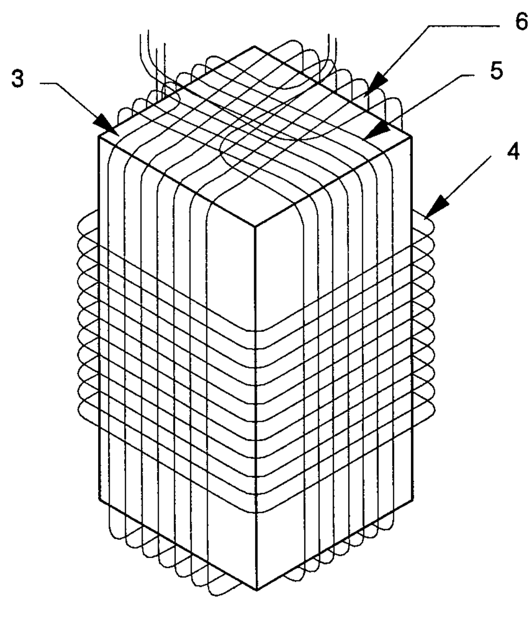

Figure 2

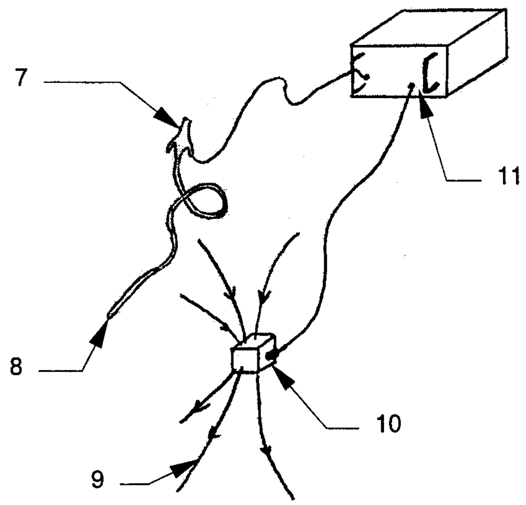

Figure 3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/01429

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 G01B7/004 G01D5/20 A61M25/095 A61B5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 G01V G01D G01B A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

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[X] Further documents are listed in the continuation of box C.

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